Whereas today, the W.K. Kellogg Foundation is 1 of the largest philanthropic institutions in the world, funding projects throughout the world in—

(1) health;

(2) education;

(3) agriculture;

(4) leadership; and

(5) youth development;

Whereas the assets of the W.K. Kellogg Foundation were nearly $6,000,000,000 when the foundation approached its 75th Anniversary in 2005;

Whereas, during those 75 years of service, the foundation donated more than $3,000,000,000 to help people help themselves;

Whereas, during the Second World War, the production facilities of the Kellogg Company were used to assist the Armed Forces in many engineering efforts;

Whereas, during that time, the products of the Kellogg Company became a common item in packages sent by families to soldiers serving overseas;

Whereas W.K. Kellogg was later awarded the Army-Navy ''E'' Flag for Excellence for his valuable contributions to the United States during the Second World War;

Whereas, throughout its history, the Kellogg Company introduced many of their most famous and successful cereals and characters, including—

(1) Tony the Tiger; and

(2) Snap, Crackle, and Pop;

Whereas, in 1969, astronauts on board the Apollo 11 breakfasted on cereal produced by the Kellogg Company during their successful mission to the moon, thereby making it the first breakfast cereal ever to reach outer space;

Whereas the Kellogg Company opened a new headquarters facility in Battle Creek;

Whereas, throughout the 1980's and 1990's, the Kellogg Company continued its commitment to social responsibility by supporting numerous organizations, including—

(1) the United Negro College Fund;

(2) the Statue of Liberty-Ellis Island renewal project; and

(3) organizations that sought to end the policy of apartheid that was enforced by the Government of South Africa;

Whereas today, the Kellogg Company produces more than 40 different cereals on 6 continents, and markets the products of the company in more than 180 countries;

Whereas the Kellogg Company employs 25,000 people throughout the world; and

Whereas the Kellogg Company currently has production facilities in 13 states, including—

(1) California;

(2) Georgia;

(3) Illinois;

(4) Kansas;

(5) Kentucky;

(6) Michigan;

(7) Nebraska;

(8) New Jersey;

(9) North Carolina;

(10) Ohio;

(11) Pennsylvania;

(12) Tennessee; and

(13) Washington: Now, therefore, be it

Resolved, That the Senate recognizes—

(1) the great contributions of Will Keith Kellogg to—

(A) the citizens of the United States; and

(B) the people of the world;

(2) the 100th anniversary of the creation of the first flaked breakfast cereal, which occurred on April 1, 2006; and

(3) the achievements of W.K. Kellogg and the benefits enjoyed by all those touched by his life.

Ms. STABENOW. Mr. President, today I am pleased to offer this resolution in honor of Will Keith Kellogg, who founded the Kellogg Company in 1906 in Battle Creek, MI. I am pleased to be joined by my colleagues, Senators Isakson, Chambliss, and Levin.

Today, Kellogg's company employs more than 25,000 people worldwide and operates production sites in thirteen states. Additionally, the Kellogg Foundation is one of the largest philanthropic institutions in the world. Last year, it celebrated its seventy-fifth anniversary and has donated more than $3 billion to health, education, agricultural, and youth-development projects.

I am proud of the work of Mr. Kellogg and the great work of both the Kellogg Company and the Kellogg Foundation. I ask for unanimous consent that the text of the bill be printed in the RECORD.

AMENDMENTS SUBMITTED AND PROPOSED

SA 4742. Mr. DORGAN (for himself and Ms. SNOWE) submitted an amendment intended to be proposed by him to the bill S. 3711, to enhance the energy independence and security of the United States by providing for exploration, development, and production activities for mineral resources in the Gulf of Mexico, and for other purposes; which was ordered to lie on the table.

SA 4743. Mr. KERRY submitted an amendment intended to be proposed by him to the bill S. 3711, supra; which was ordered to lie on the table.

SA 4744. Mr. KERRY (for himself and Mr. JEFFORDS) submitted an amendment intended to be proposed by him to the bill S. 3711, supra; which was ordered to lie on the table.

SA 4745. Mr. KERRY submitted an amendment intended to be proposed by him to the bill S. 3711, supra; which was ordered to lie on the table.

SA 4746. Mr. SMITH (for himself, Mr. MENENDEZ, Ms. SNOWE, Mr. KERRY, Mr. SALAZAR, Ms. CANTWELL, Mr. LIEBERMAN, Mr. KENNEDY, Mr. ALLARD, Mr. WYDEN, Mrs. CLINTON, and Mr. DODD) submitted an amendment intended to be proposed by him to the bill S. 3711, supra; which was ordered to lie on the table .

SA 4747. Mr. WARNER submitted an amendment intended to be proposed by him to the bill S. 3711, supra; which was ordered to lie on the table.

SA 4748. Mr. ALLEN submitted an amendment intended to be proposed to amendment SA 4713 proposed by Mr. FRIST to the bill S. 3711, supra; which was ordered to lie on the table.

TEXT OF AMENDMENTS

SA 4742. Mr. DORGAN (for himself and Ms. SNOWE) submitted an amendment intended to be proposed by him to the bill S. 3711, to enhance the energy independence and security of the United States by providing for exploration, development, and production activities for mineral resources in the Gulf of Mexico, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE ____—IMPORTATION OF PRESCRIPTION DRUGS

SEC. ___1. SHORT TITLE.

This title may be cited as the ''Pharmaceutical Market Access and Drug Safety Act of 2006''.

SEC. ___2. FINDINGS.

Congress finds that—

(1) Americans unjustly pay up to 5 times more to fill their prescriptions than consumers in other countries;

(2) the United States is the largest market for pharmaceuticals in the world, yet American consumers pay the highest prices for brand pharmaceuticals in the world;

(3) a prescription drug is neither safe nor effective to an individual who cannot afford it;

(4) allowing and structuring the importation of prescription drugs to ensure access to safe and affordable drugs approved by the Food and Drug Administration will provide a level of safety to American consumers that they do not currently enjoy;

(5) American spend more than $200,000,000,000 on prescription drugs every year;

(6) the Congressional Budget Office has found that the cost of prescription drugs are between 35 to 55 percent less in other highly-developed countries than in the United States; and

(7) promoting competitive market pricing would both contribute to health care savings and allow greater access to therapy, improving health and saving lives.

SEC. ___3. REPEAL OF CERTAIN SECTION REGARDING IMPORTATION OF PRESCRIPTION DRUGS.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804.

SEC. ___4. IMPORTATION OF PRESCRIPTION DRUGS; WAIVER OF CERTAIN IMPORT RESTRICTIONS.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.), as amended by section ___3, is further amended by inserting after section 803 the following:

''SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF PRESCRIPTION DRUGS.

''(a) IMPORTATION OF PRESCRIPTION DRUGS.—

''(1) IN GENERAL.—In the case of qualifying drugs imported or offered for import into the United States from registered exporters or by registered importers—

''(A) the limitation on importation that is established in section 801(d)(1) is waived; and

''(B) the standards referred to in section 801(a) regarding admission of the drugs are subject to subsection (g) of this section (including with respect to qualifying drugs to which section 801(d)(1) does not apply).

''(2) IMPORTERS.—A qualifying drug may not be imported under paragraph (1) unless—

''(A) the drug is imported by a pharmacy, group of pharmacies, or a wholesaler that is a registered importer; or

''(B) the drug is imported by an individual for personal use or for the use of a family member of the individual (not for resale) from a registered exporter.

''(3) RULE OF CONSTRUCTION.—This section shall apply only with respect to a drug that is imported or offered for import into the United States—

''(A) by a registered importer; or

''(B) from a registered exporter to an individual.

''(4) DEFINITIONS.—

''(A) REGISTERED EXPORTER; REGISTERED IMPORTER.—For purposes of this section:

''(i) The term 'registered exporter' means an exporter for which a registration under subsection (b) has been approved and is in effect.

''(ii) The term 'registered importer' means a pharmacy, group of pharmacies, or a wholesaler for which a registration under subsection (b) has been approved and is in effect.

''(iii) The term 'registration condition' means a condition that must exist for a registration under subsection (b) to be approved.

''(B) QUALIFYING DRUG.—For purposes of this section, the term 'qualifying drug' means a drug for which there is a corresponding U.S. label drug.

''(C) U.S. LABEL DRUG.—For purposes of this section, the term 'U.S. label drug' means a prescription drug that—

''(i) with respect to a qualifying drug, has the same active ingredient or ingredients, route of administration, dosage form, and strength as the qualifying drug;

''(ii) with respect to the qualifying drug, is manufactured by or for the person that manufactures the qualifying drug;

''(iii) is approved under section 505(c); and

''(iv) is not—

''(I) a controlled substance, as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802);

''(II) a biological product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262), including—

''(aa) a therapeutic DNA plasmid product;

''(bb) a therapeutic synthetic peptide product;

''(cc) a monoclonal antibody product for in vivo use; and

''(dd) a therapeutic recombinant DNA-derived product;

''(III) an infused drug, including a peritoneal dialysis solution;

''(IV) an injected drug;

''(V) a drug that is inhaled during surgery;

''(VI) a drug that is the listed drug referred to in 2 or more abbreviated new drug applications under which the drug is commercially marketed; or

''(VII) a sterile opthlamic drug intended for topical use on or in the eye.

''(D) OTHER DEFINITIONS.—For purposes of this section:

''(i)(I) The term 'exporter' means a person that is in the business of exporting a drug to individuals in the United States from Canada or from a permitted country designated by the Secretary under subclause (II), or that, pursuant to submitting a registration under subsection (b), seeks to be in such business.

''(II) The Secretary shall designate a permitted country under subparagraph (E) (other than Canada) as a country from which an exporter may export a drug to individuals in the United States if the Secretary determines that—

''(aa) the country has statutory or regulatory standards that are equivalent to the standards in the United States and Canada with respect to—

''(AA) the training of pharmacists;

''(BB) the practice of pharmacy; and

''(CC) the protection of the privacy of personal medical information; and

''(bb) the importation of drugs to individuals in the United States from the country will not adversely affect public health.

''(ii) The term 'importer' means a pharmacy, a group of pharmacies, or a wholesaler that is in the business of importing a drug into the United States or that, pursuant to submitting a registration under subsection (b), seeks to be in such business.

''(iii) The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

''(iv) The term 'pharmacy' means a person that—

''(I) is licensed by a State to engage in the business of selling prescription drugs at retail; and

''(II) employs 1 or more pharmacists.

''(v) The term 'prescription drug' means a drug that is described in section 503(b)(1).

''(vi) The term 'wholesaler'—

''(I) means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A); and

''(II) does not include a person authorized to import drugs under section 801(d)(1).

''(E) PERMITTED COUNTRY.—The term 'permitted country' means—

''(i) Australia;

''(ii) Canada;

''(iii) a member country of the European Union, but does not include a member country with respect to which—

''(I) the country's Annex to the Treaty of Accession to the European Union 2003 includes a transitional measure for the regulation of human pharmaceutical products that has not expired; or

''(II) the Secretary determines that the requirements described in subclauses (I) and (II) of clause (vii) will not be met by the date on which such transitional measure for the regulation of human pharmaceutical products expires;

''(iv) Japan;

''(v) New Zealand;

''(vi) Switzerland; and

''(vii) a country in which the Secretary determines the following requirements are met:

''(I) The country has statutory or regulatory requirements—

''(aa) that require the review of drugs for safety and effectiveness by an entity of the government of the country;

''(bb) that authorize the approval of only those drugs that have been determined to be safe and effective by experts employed by or acting on behalf of such entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs on the basis of adequate and well-controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs;

''(cc) that require the methods used in, and the facilities and controls used for the manufacture, processing, and packing of drugs in the country to be adequate to preserve their identity, quality, purity, and strength;

''(dd) for the reporting of adverse reactions to drugs and procedures to withdraw approval and remove drugs found not to be safe or effective; and

''(ee) that require the labeling and promotion of drugs to be in accordance with the approval of the drug.

''(II) The valid marketing authorization system in the country is equivalent to the systems in the countries described in clauses (i) through (vi).

''(III) The importation of drugs to the United States from the country will not adversely affect public health.

''(b) REGISTRATION OF IMPORTERS AND EXPORTERS.—

''(1) REGISTRATION OF IMPORTERS AND EXPORTERS.—A registration condition is that the importer or exporter involved (referred to in this subsection as a 'registrant') submits to the Secretary a registration containing the following:

''(A)(i) In the case of an exporter, the name of the exporter and an identification of all places of business of the exporter that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the exporter.

''(ii) In the case of an importer, the name of the importer and an identification of the places of business of the importer at which the importer initially receives a qualifying drug after importation (which shall not exceed 3 places of business except by permission of the Secretary).

''(B) Such information as the Secretary determines to be necessary to demonstrate that the registrant is in compliance with registration conditions under—

''(i) in the case of an importer, subsections (c), (d), (e), (g), and (j) (relating to the sources of imported qualifying drugs; the inspection of facilities of the importer; the payment of fees; compliance with the standards referred to in section 801(a); and maintenance of records and samples); or

''(ii) in the case of an exporter, subsections (c), (d), (f), (g), (h), (i), and (j) (relating to the sources of exported qualifying drugs; the inspection of facilities of the exporter and the marking of compliant shipments; the payment of fees; and compliance with the standards referred to in section 801(a); being licensed as a pharmacist; conditions for individual importation; and maintenance of records and samples).

''(C) An agreement by the registrant that the registrant will not under subsection (a) import or export any drug that is not a qualifying drug.

''(D) An agreement by the registrant to—

''(i) notify the Secretary of a recall or withdrawal of a qualifying drug distributed in a permitted country that the registrant has exported or imported, or intends to export or import, to the United States under subsection (a);

''(ii) provide for the return to the registrant of such drug; and

''(iii) cease, or not begin, the exportation or importation of such drug unless the Secretary has notified the registrant that exportation or importation of such drug may proceed.

''(E) An agreement by the registrant to ensure and monitor compliance with each registration condition, to promptly correct any noncompliance with such a condition, and to promptly report to the Secretary any such noncompliance.

''(F) A plan describing the manner in which the registrant will comply with the agreement under subparagraph (E).

''(G) An agreement by the registrant to enforce a contract under subsection (c)(3)(B) against a party in the chain of custody of a qualifying drug with respect to the authority of the Secretary under clauses (ii) and (iii) of that subsection.

''(H) An agreement by the registrant to notify the Secretary not more than 30 days before the registrant intends to make the change, of—

''(i) any change that the registrant intends to make regarding information provided under subparagraph (A) or (B); and

''(ii) any change that the registrant intends to make in the compliance plan under subparagraph (F).

''(I) In the case of an exporter—

''(i) An agreement by the exporter that a qualifying drug will not under subsection (a) be exported to any individual not authorized pursuant to subsection (a)(2)(B) to be an importer of such drug.

''(ii) An agreement to post a bond, payable to the Treasury of the United States that is equal in value to the lesser of—

''(I) the value of drugs exported by the exporter to the United States in a typical 4-week period over the course of a year under this section; or

''(II) $1,000,000;

''(iii) An agreement by the exporter to comply with applicable provisions of Canadian law, or the law of the permitted country

designated under subsection (a)(4)(D)(i)(II) in which the exporter is located, that protect the privacy of personal information with respect to each individual importing a prescription drug from the exporter under subsection (a)(2)(B).

''(iv) An agreement by the exporter to report to the Secretary—

''(I) not later than August 1 of each fiscal year, the total price and the total volume of drugs exported to the United States by the exporter during the 6-month period from January 1 through June 30 of that year; and

''(II) not later than January 1 of each fiscal year, the total price and the total volume of drugs exported to the United States by the exporter during the previous fiscal year.

''(J) In the case of an importer, an agreement by the importer to report to the Secretary—

''(i) not later than August 1 of each fiscal year, the total price and the total volume of drugs imported to the United States by the importer during the 6-month period from January 1 through June 30 of that fiscal year; and

''(ii) not later than January 1 of each fiscal year, the total price and the total volume of drugs imported to the United States by the importer during the previous fiscal year.

''(K) Such other provisions as the Secretary may require by regulation to protect the public health while permitting—

''(i) the importation by pharmacies, groups of pharmacies, and wholesalers as registered importers of qualifying drugs under subsection (a); and

''(ii) importation by individuals of qualifying drugs under subsection (a).

''(2) APPROVAL OR DISAPPROVAL OF REGISTRATION.—

''(A) IN GENERAL.—Not later than 90 days after the date on which a registrant submits to the Secretary a registration under paragraph (1), the Secretary shall notify the registrant whether the registration is approved or is disapproved. The Secretary shall disapprove a registration if there is reason to believe that the registrant is not in compliance with one or more registration conditions, and shall notify the registrant of such reason. In the case of a disapproved registration, the Secretary shall subsequently notify the registrant that the registration is approved if the Secretary determines that the registrant is in compliance with such conditions.

''(B) CHANGES IN REGISTRATION INFORMATION.—Not later than 30 days after receiving a notice under paragraph (1)(H) from a registrant, the Secretary shall determine whether the change involved affects the approval of the registration of the registrant under paragraph (1), and shall inform the registrant of the determination.

''(3) PUBLICATION OF CONTACT INFORMATION FOR REGISTERED EXPORTERS.—Through the Internet website of the Food and Drug Administration and a toll-free telephone number, the Secretary shall make readily available to the public a list of registered exporters, including contact information for the exporters. Promptly after the approval of a registration submitted under paragraph (1), the Secretary shall update the Internet website and the information provided through the toll-free telephone number accordingly.

''(4) SUSPENSION AND TERMINATION.—

''(A) SUSPENSION.—With respect to the effectiveness of a registration submitted under paragraph (1):

''(i) Subject to clause (ii), the Secretary may suspend the registration if the Secretary determines, after notice and opportunity for a hearing, that the registrant has failed to maintain substantial compliance with a registration condition.

''(ii) If the Secretary determines that, under color of the registration, the exporter has exported a drug or the importer has imported a drug that is not a qualifying drug, or a drug that does not comply with subsection (g)(2)(A) or (g)(4), or has exported a qualifying drug to an individual in violation of subsection (i)(2)(F), the Secretary shall immediately suspend the registration. A suspension under the preceding sentence is not subject to the provision by the Secretary of prior notice, and the Secretary shall provide to the registrant an opportunity for a hearing not later than 10 days after the date on which the registration is suspended.

''(iii) The Secretary may reinstate the registration, whether suspended under clause (i) or (ii), if the Secretary determines that the registrant has demonstrated that further violations of registration conditions will not occur.

''(B) TERMINATION.—The Secretary, after notice and opportunity for a hearing, may terminate the registration under paragraph (1) of a registrant if the Secretary determines that the registrant has engaged in a pattern or practice of violating 1 or more registration conditions, or if on 1 or more occasions the Secretary has under subparagraph (A)(ii) suspended the registration of the registrant. The Secretary may make the termination permanent, or for a fixed period of not less than 1 year. During the period in which the registration is terminated, any registration submitted under paragraph (1) by the registrant, or a person that is a partner in the export or import enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

''(5) DEFAULT OF BOND.—A bond required to be posted by an exporter under paragraph (1)(I)(ii) shall be defaulted and paid to the Treasury of the United States if, after opportunity for an informal hearing, the Secretary determines that the exporter has—

''(A) exported a drug to the United States that is not a qualifying drug or that is not in compliance with subsection (g)(2)(A), (g)(4), or (i); or

''(B) failed to permit the Secretary to conduct an inspection described under subsection (d).

''(c) SOURCES OF QUALIFYING DRUGS.—A registration condition is that the exporter or importer involved agrees that a qualifying drug will under subsection (a) be exported or imported into the United States only if there is compliance with the following:

''(1) The drug was manufactured in an establishment—

''(A) required to register under subsection (h) or (i) of section 510; and

''(B)(i) inspected by the Secretary; or

''(ii) for which the Secretary has elected to rely on a satisfactory report of a good manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent under a mutual recognition agreement, as provided for under section 510(i)(3), section 803, or part 26 of title 21, Code of Federal Regulations (or any corresponding successor rule or regulation).

''(2) The establishment is located in any country, and the establishment manufactured the drug for distribution in the United States or for distribution in 1 or more of the permitted countries (without regard to whether in addition the drug is manufactured for distribution in a foreign country that is not a permitted country).

''(3) The exporter or importer obtained the drug—

''(A) directly from the establishment; or

''(B) directly from an entity that, by contract with the exporter or importer—

''(i) provides to the exporter or importer a statement (in such form and containing such information as the Secretary may require) that, for the chain of custody from the establishment, identifies each prior sale, purchase, or trade of the drug (including the date of the transaction and the names and addresses of all parties to the transaction);

''(ii) agrees to permit the Secretary to inspect such statements and related records to determine their accuracy;

''(iii) agrees, with respect to the qualifying drugs involved, to permit the Secretary to inspect warehouses and other facilities, including records, of the entity for purposes of determining whether the facilities are in compliance with any standards under this Act that are applicable to facilities of that type in the United States; and

''(iv) has ensured, through such contractual relationships as may be necessary, that the Secretary has the same authority regarding other parties in the chain of custody from the establishment that the Secretary has under clauses (ii) and (iii) regarding such entity.

''(4)(A) The foreign country from which the importer will import the drug is a permitted country; or

''(B) The foreign country from which the exporter will export the drug is the permitted country in which the exporter is located.

''(5) During any period in which the drug was not in the control of the manufacturer of the drug, the drug did not enter any country that is not a permitted country.

''(6) The exporter or importer retains a sample of each lot of the drug sufficient for testing by the Secretary.

''(d) INSPECTION OF FACILITIES; MARKING OF SHIPMENTS.—

''(1) INSPECTION OF FACILITIES.—A registration condition is that, for the purpose of assisting the Secretary in determining whether the exporter involved is in compliance with all other registration conditions—

''(A) the exporter agrees to permit the Secretary—

''(i) to conduct onsite inspections, including monitoring on a day-to-day basis, of places of business of the exporter that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the exporter;

''(ii) to have access, including on a day-to-day basis, to—

''(I) records of the exporter that relate to the export of such drugs, including financial records; and

''(II) samples of such drugs;

''(iii) to carry out the duties described in paragraph (3); and

''(iv) to carry out any other functions determined by the Secretary to be necessary regarding the compliance of the exporter; and

''(B) the Secretary has assigned 1 or more employees of the Secretary to carry out the functions described in this subsection for the Secretary randomly, but not less than 12 times annually, on the premises of places of businesses referred to in subparagraph (A)(i), and such an assignment remains in effect on a continuous basis.

''(2) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the exporter involved agrees to affix to each shipping container of qualifying drugs exported under subsection (a) such markings as the Secretary determines to be necessary to identify the shipment as being in compliance with all registration conditions. Markings under the preceding sentence shall—

''(A) be designed to prevent affixation of the markings to any shipping container that is not authorized to bear the markings; and

''(B) include anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies.

''(3) CERTAIN DUTIES RELATING TO EXPORTERS.—Duties of the Secretary with respect to an exporter include the following:

''(A) Inspecting, randomly, but not less than 12 times annually, the places of business of the exporter at which qualifying drugs are stored and from which qualifying drugs are shipped.

''(B) During the inspections under subparagraph (A), verifying the chain of custody of a statistically significant sample of qualifying drugs from the establishment in which the drug was manufactured to the exporter, which shall be accomplished or supplemented by the use of anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies, except that a drug that lacks such technologies from the point of manufacture shall not for that reason be excluded from importation by an exporter.

''(C) Randomly reviewing records of exports to individuals for the purpose of determining whether the drugs are being imported by the individuals in accordance with the conditions under subsection (i). Such reviews shall be conducted in a manner that will result in a statistically significant determination of compliance with all such conditions.

''(D) Monitoring the affixing of markings under paragraph (2).

''(E) Inspecting as the Secretary determines is necessary the warehouses and other facilities, including records, of other parties in the chain of custody of qualifying drugs.

''(F) Determining whether the exporter is in compliance with all other registration conditions.

''(4) PRIOR NOTICE OF SHIPMENTS.—A registration condition is that, not less than 8 hours and not more than 5 days in advance of the time of the importation of a shipment of qualifying drugs, the importer involved agrees to submit to the Secretary a notice with respect to the shipment of drugs to be imported or offered for import into the United States under subsection (a). A notice under the preceding sentence shall include—

''(A) the name and complete contact information of the person submitting the notice;

''(B) the name and complete contact information of the importer involved;

''(C) the identity of the drug, including the established name of the drug, the quantity of the drug, and the lot number assigned by the manufacturer;

''(D) the identity of the manufacturer of the drug, including the identity of the establishment at which the drug was manufactured;

''(E) the country from which the drug is shipped;

''(F) the name and complete contact information for the shipper of the drug;

''(G) anticipated arrival information, including the port of arrival and crossing location within that port, and the date and time;

''(H) a summary of the chain of custody of the drug from the establishment in which the drug was manufactured to the importer;

''(I) a declaration as to whether the Secretary has ordered that importation of the drug from the permitted country cease under subsection (g)(2)(C) or (D); and

''(J) such other information as the Secretary may require by regulation.

''(5) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the importer involved agrees, before wholesale distribution (as defined in section 503(e)) of a qualifying drug that has been imported under subsection (a), to affix to each container of such drug such markings or other technology as the Secretary determines necessary to identify the shipment as being in compliance with all registration conditions, except that the markings or other technology shall not be required on a drug that bears comparable, compatible markings or technology from the manufacturer of the drug. Markings or other technology under the preceding sentence shall—

''(A) be designed to prevent affixation of the markings or other technology to any container that is not authorized to bear the markings; and

''(B) shall include anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of such technologies.

''(6) CERTAIN DUTIES RELATING TO IMPORTERS.—Duties of the Secretary with respect to an importer include the following:

''(A) Inspecting, randomly, but not less than 12 times annually, the places of business of the importer at which a qualifying drug is initially received after importation.

''(B) During the inspections under subparagraph (A), verifying the chain of custody of a statistically significant sample of qualifying drugs from the establishment in which the drug was manufactured to the importer, which shall be accomplished or supplemented by the use of anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies, except that a drug that lacks such technologies from the point of manufacture shall not for that reason be excluded from importation by an importer.

''(C) Reviewing notices under paragraph (4).

''(D) Inspecting as the Secretary determines is necessary the warehouses and other facilities, including records of other parties in the chain of custody of qualifying drugs.

''(E) Determining whether the importer is in compliance with all other registration conditions.

''(e) IMPORTER FEES.—

''(1) REGISTRATION FEE.—A registration condition is that the importer involved pays to the Secretary a fee of $10,000 due on the date on which the importer first submits the registration to the Secretary under subsection (b).

''(2) INSPECTION FEE.—A registration condition is that the importer involved pays a fee to the Secretary in accordance with this subsection. Such fee shall be paid not later than October 1 and April 1 of each fiscal year in the amount provided for under paragraph (3).

''(3) AMOUNT OF INSPECTION FEE.—

''(A) AGGREGATE TOTAL OF FEES.—Not later than 30 days before the start of each fiscal year, the Secretary, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, shall establish an aggregate total of fees to be collected under paragraph (2) for importers for that fiscal year that is sufficient, and not more than necessary, to pay the costs for that fiscal year of administering this section with respect to registered importers, including the costs associated with—

''(i) inspecting the facilities of registered importers, and of other entities in the chain of custody of a qualifying drug as necessary, under subsection (d)(6);

''(ii) developing, implementing, and operating under such subsection an electronic system for submission and review of the notices required under subsection (d)(4) with respect to shipments of qualifying drugs under subsection (a) to assess compliance with all registration conditions when such shipments are offered for import into the United States; and

''(iii) inspecting such shipments as necessary, when offered for import into the United States to determine if such a shipment should be refused admission under subsection (g)(5).

''(B) LIMITATION.—Subject to subparagraph (C), the aggregate total of fees collected under paragraph (2) for a fiscal year shall not exceed 2.5 percent of the total price of qualifying drugs imported during that fiscal year into the United States by registered importers under subsection (a).

''(C) TOTAL PRICE OF DRUGS.—

''(i) ESTIMATE.—For the purposes of complying with the limitation described in subparagraph (B) when establishing under subparagraph (A) the aggregate total of fees to be collected under paragraph (2) for a fiscal year, the Secretary shall estimate the total price of qualifying drugs imported into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs imported by each registered importer during the 6-month period from January 1 through June 30 of the previous fiscal year, as reported to the Secretary by each registered importer under subsection (b)(1)(J).

''(ii) CALCULATION.—Not later than March 1 of the fiscal year that follows the fiscal year for which the estimate under clause (i) is made, the Secretary shall calculate the total price of qualifying drugs imported into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs imported by each registered importer during that fiscal year, as reported to the Secretary by each registered importer under subsection (b)(1)(J).

''(iii) ADJUSTMENT.—If the total price of qualifying drugs imported into the United States by registered importers during a fiscal year as calculated under clause (ii) is less than the aggregate total of fees collected under paragraph (2) for that fiscal year, the Secretary shall provide for a pro-rata reduction in the fee due from each registered importer on April 1 of the subsequent fiscal year so that the limitation described in subparagraph (B) is observed.

''(D) INDIVIDUAL IMPORTER FEE.—Subject to the limitation described in subparagraph (B), the fee under paragraph (2) to be paid on October 1 and April 1 by an importer shall be an amount that is proportional to a reasonable estimate by the Secretary of the semiannual share of the importer of the volume of qualifying drugs imported by importers under subsection (a).

''(4) USE OF FEES.—

''(A) IN GENERAL.—Subject to appropriations Acts, fees collected by the Secretary under paragraphs (1) and (2) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration until expended (without fiscal year limitation), and the Secretary may, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, transfer some proportion of such fees to the appropriation account for salaries and expenses of the Bureau of Customs and Border Protection until expended (without fiscal year limitation).

''(B) SOLE PURPOSE.—Fees collected by the Secretary under paragraphs (1) and (2) are only available to the Secretary and, if transferred, to the Secretary of Homeland Security, and are for the sole purpose of paying the costs referred to in paragraph (3)(A).

''(5) COLLECTION OF FEES.—In any case where the Secretary does not receive payment of a fee assessed under paragraph (1) or (2) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(f) EXPORTER FEES.—

''(1) REGISTRATION FEE.—A registration condition is that the exporter involved pays to the Secretary a fee of $10,000 due on the

date on which the exporter first submits that registration to the Secretary under subsection (b).

''(2) INSPECTION FEE.—A registration condition is that the exporter involved pays a fee to the Secretary in accordance with this subsection. Such fee shall be paid not later than October 1 and April 1 of each fiscal year in the amount provided for under paragraph (3).

''(3) AMOUNT OF INSPECTION FEE.—

''(A) AGGREGATE TOTAL OF FEES.—Not later than 30 days before the start of each fiscal year, the Secretary, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, shall establish an aggregate total of fees to be collected under paragraph (2) for exporters for that fiscal year that is sufficient, and not more than necessary, to pay the costs for that fiscal year of administering this section with respect to registered exporters, including the costs associated with—

''(i) inspecting the facilities of registered exporters, and of other entities in the chain of custody of a qualifying drug as necessary, under subsection (d)(3);

''(ii) developing, implementing, and operating under such subsection a system to screen marks on shipments of qualifying drugs under subsection (a) that indicate compliance with all registration conditions, when such shipments are offered for import into the United States; and

''(iii) screening such markings, and inspecting such shipments as necessary, when offered for import into the United States to determine if such a shipment should be refused admission under subsection (g)(5).

''(B) LIMITATION.—Subject to subparagraph (C), the aggregate total of fees collected under paragraph (2) for a fiscal year shall not exceed 2.5 percent of the total price of qualifying drugs imported during that fiscal year into the United States by registered exporters under subsection (a).

''(C) TOTAL PRICE OF DRUGS.—

''(i) ESTIMATE.—For the purposes of complying with the limitation described in subparagraph (B) when establishing under subparagraph (A) the aggregate total of fees to be collected under paragraph (2) for a fiscal year, the Secretary shall estimate the total price of qualifying drugs imported into the United States by registered exporters during that fiscal year by adding the total price of qualifying drugs exported by each registered exporter during the 6-month period from January 1 through June 30 of the previous fiscal year, as reported to the Secretary by each registered exporter under subsection (b)(1)(I)(iv).

''(ii) CALCULATION.—Not later than March 1 of the fiscal year that follows the fiscal year for which the estimate under clause (i) is made, the Secretary shall calculate the total price of qualifying drugs imported into the United States by registered exporters during that fiscal year by adding the total price of qualifying drugs exported by each registered exporter during that fiscal year, as reported to the Secretary by each registered exporter under subsection (b)(1)(I)(iv).

''(iii) ADJUSTMENT.—If the total price of qualifying drugs imported into the United States by registered exporters during a fiscal year as calculated under clause (ii) is less than the aggregate total of fees collected under paragraph (2) for that fiscal year, the Secretary shall provide for a pro-rata reduction in the fee due from each registered exporter on April 1 of the subsequent fiscal year so that the limitation described in subparagraph (B) is observed.

''(D) INDIVIDUAL EXPORTER FEE.—Subject to the limitation described in subparagraph (B), the fee under paragraph (2) to be paid on October 1 and April 1 by an exporter shall be an amount that is proportional to a reasonable estimate by the Secretary of the semiannual share of the exporter of the volume of qualifying drugs exported by exporters under subsection (a).

''(4) USE OF FEES.—

''(A) IN GENERAL.—Subject to appropriations Acts, fees collected by the Secretary under paragraphs (1) and (2) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration until expended (without fiscal year limitation), and the Secretary may, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, transfer some proportion of such fees to the appropriation account for salaries and expenses of the Bureau of Customs and Border Protection until expended (without fiscal year limitation).

''(B) SOLE PURPOSE.—Fees collected by the Secretary under paragraphs (1) and (2) are only available to the Secretary and, if transferred, to the Secretary of Homeland Security, and are for the sole purpose of paying the costs referred to in paragraph (3)(A).

''(5) COLLECTION OF FEES.—In any case where the Secretary does not receive payment of a fee assessed under paragraph (1) or (2) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(g) COMPLIANCE WITH SECTION 801(a).—

''(1) IN GENERAL.—A registration condition is that each qualifying drug exported under subsection (a) by the registered exporter involved or imported under subsection (a) by the registered importer involved is in compliance with the standards referred to in section 801(a) regarding admission of the drug into the United States, subject to paragraphs (2), (3), and (4).

''(2) SECTION 505; APPROVAL STATUS.—

''(A) IN GENERAL.—A qualifying drug that is imported or offered for import under subsection (a) shall comply with the conditions established in the approved application under section 505(b) for the U.S. label drug as described under this subsection.

''(B) NOTICE BY MANUFACTURER; GENERAL PROVISIONS.—

''(i) IN GENERAL.—The person that manufactures a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country shall in accordance with this paragraph submit to the Secretary a notice that—

''(I) includes each difference in the qualifying drug from a condition established in the approved application for the U.S. label drug beyond—

''(aa) the variations provided for in the application; and

''(bb) any difference in labeling (except ingredient labeling); or

''(II) states that there is no difference in the qualifying drug from a condition established in the approved application for the U.S. label drug beyond—

''(aa) the variations provided for in the application; and

''(bb) any difference in labeling (except ingredient labeling).

''(ii) INFORMATION IN NOTICE.—A notice under clause (i)(I) shall include the information that the Secretary may require under section 506A, any additional information the Secretary may require (which may include data on bioequivalence if such data are not required under section 506A), and, with respect to the permitted country that approved the qualifying drug for commercial distribution, or with respect to which such approval is sought, include the following:

''(I) The date on which the qualifying drug with such difference was, or will be, introduced for commercial distribution in the permitted country.

''(II) Information demonstrating that the person submitting the notice has also notified the government of the permitted country in writing that the person is submitting to the Secretary a notice under clause (i)(I), which notice describes the difference in the qualifying drug from a condition established in the approved application for the U.S. label drug.

''(III) The information that the person submitted or will submit to the government of the permitted country for purposes of obtaining approval for commercial distribution of the drug in the country which, if in a language other than English, shall be accompanied by an English translation verified to be complete and accurate, with the name, address, and a brief statement of the qualifications of the person that made the translation.

''(iii) CERTIFICATIONS.—The chief executive officer and the chief medical officer of the manufacturer involved shall each certify in the notice under clause (i) that—

''(I) the information provided in the notice is complete and true; and

''(II) a copy of the notice has been provided to the Federal Trade Commission and to the State attorneys general.

''(iv) FEE.—If a notice submitted under clause (i) includes a difference that would, under section 506A, require the submission of a supplemental application if made as a change to the U.S. label drug, the person that submits the notice shall pay to the Secretary a fee in the same amount as would apply if the person were paying a fee pursuant to section 736(a)(1)(A)(ii). Subject to appropriations Acts, fees collected by the Secretary under the preceding sentence are available only to the Secretary and are for the sole purpose of paying the costs of reviewing notices submitted under clause (i).

''(v) TIMING OF SUBMISSION OF NOTICES.—

''(I) PRIOR APPROVAL NOTICES.—A notice under clause (i) to which subparagraph (C) applies shall be submitted to the Secretary not later than 120 days before the qualifying drug with the difference is introduced for commercial distribution in a permitted country, unless the country requires that distribution of the qualifying drug with the difference begin less than 120 days after the country requires the difference.

''(II) OTHER APPROVAL NOTICES.—A notice under clause (i) to which subparagraph (D) applies shall be submitted to the Secretary not later than the day on which the qualifying drug with the difference is introduced for commercial distribution in a permitted country.

''(III) OTHER NOTICES.—A notice under clause (i) to which subparagraph (E) applies shall be submitted to the Secretary on the date that the qualifying drug is first introduced for commercial distribution in a permitted country and annually thereafter.

''(vi) REVIEW BY SECRETARY.—

''(I) IN GENERAL.—In this paragraph, the difference in a qualifying drug that is submitted in a notice under clause (i) from the U.S. label drug shall be treated by the Secretary as if it were a manufacturing change to the U.S. label drug under section 506A.

''(II) STANDARD OF REVIEW.—Except as provided in subclause (III), the Secretary shall review and approve or disapprove the difference in a notice submitted under clause (i), if required under section 506A, using the safe and effective standard for approving or disapproving a manufacturing change under section 506A.

''(III) BIOEQUIVALENCE.—If the Secretary would approve the difference in a notice submitted under clause (i) using the safe and effective standard under section 506A and if the Secretary determines that the qualifying

drug is not bioequivalent to the U.S. label drug, the Secretary shall—

''(aa) include in the labeling provided under paragraph (3) a prominent advisory that the qualifying drug is safe and effective but is not bioequivalent to the U.S. label drug if the Secretary determines that such an advisory is necessary for health care practitioners and patients to use the qualifying drug safely and effectively; or

''(bb) decline to approve the difference if the Secretary determines that the availability of both the qualifying drug and the U.S. label drug would pose a threat to the public health.

''(IV) REVIEW BY THE SECRETARY.—The Secretary shall review and approve or disapprove the difference in a notice submitted under clause (i), if required under section 506A, not later than 120 days after the date on which the notice is submitted.

''(V) ESTABLISHMENT INSPECTION.—If review of such difference would require an inspection of the establishment in which the qualifying drug is manufactured—

''(aa) such inspection by the Secretary shall be authorized; and

''(bb) the Secretary may rely on a satisfactory report of a good manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent under a mutual recognition agreement, as provided under section 510(i)(3), section 803, or part 26 of title 21, Code of Federal Regulations (or any corresponding successor rule or regulation).

''(vii) PUBLICATION OF INFORMATION ON NOTICES.—

''(I) IN GENERAL.—Through the Internet website of the Food and Drug Administration and a toll-free telephone number, the Secretary shall readily make available to the public a list of notices submitted under clause (i).

''(II) CONTENTS.—The list under subclause (I) shall include the date on which a notice is submitted and whether—

''(aa) a notice is under review;

''(bb) the Secretary has ordered that importation of the qualifying drug from a permitted country cease; or

''(cc) the importation of the drug is permitted under subsection (a).

''(III) UPDATE.—The Secretary shall promptly update the Internet website with any changes to the list.

''(C) NOTICE; DRUG DIFFERENCE REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (B)(i) that includes a difference that would, under section 506A(c) or (d)(3)(B)(i), require the approval of a supplemental application before the difference could be made to the U.S. label drug the following shall occur:

''(i) Promptly after the notice is submitted, the Secretary shall notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general that the notice has been submitted with respect to the qualifying drug involved.

''(ii) If the Secretary has not made a determination whether such a supplemental application regarding the U.S. label drug would be approved or disapproved by the date on which the qualifying drug involved is to be introduced for commercial distribution in a permitted country, the Secretary shall—

''(I) order that the importation of the qualifying drug involved from the permitted country not begin until the Secretary completes review of the notice; and

''(II) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the order.

''(iii) If the Secretary determines that such a supplemental application regarding the U.S. label drug would not be approved, the Secretary shall—

''(I) order that the importation of the qualifying drug involved from the permitted country cease, or provide that an order under clause (ii), if any, remains in effect;

''(II) notify the permitted country that approved the qualifying drug for commercial distribution of the determination; and

''(III) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

''(iv) If the Secretary determines that such a supplemental application regarding the U.S. label drug would be approved, the Secretary shall—

''(I) vacate the order under clause (ii), if any;

''(II) consider the difference to be a variation provided for in the approved application for the U.S. label drug;

''(III) permit importation of the qualifying drug under subsection (a); and

''(IV) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

''(D) NOTICE; DRUG DIFFERENCE NOT REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (B)(i) that includes a difference that would, under section 506A(d)(3)(B)(ii), not require the approval of a supplemental application before the difference could be made to the U.S. label drug the following shall occur:

''(i) During the period in which the notice is being reviewed by the Secretary, the authority under this subsection to import the qualifying drug involved continues in effect.

''(ii) If the Secretary determines that such a supplemental application regarding the U.S. label drug would not be approved, the Secretary shall—

''(I) order that the importation of the qualifying drug involved from the permitted country cease;

''(II) notify the permitted country that approved the qualifying drug for commercial distribution of the determination; and

''(III) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

''(iii) If the Secretary determines that such a supplemental application regarding the U.S. label drug would be approved, the difference shall be considered to be a variation provided for in the approved application for the U.S. label drug.

''(E) NOTICE; DRUG DIFFERENCE NOT REQUIRING APPROVAL; NO DIFFERENCE.—In the case of a notice under subparagraph (B)(i) that includes a difference for which, under section 506A(d)(1)(A), a supplemental application would not be required for the difference to be made to the U.S. label drug, or that states that there is no difference, the Secretary—

''(i) shall consider such difference to be a variation provided for in the approved application for the U.S. label drug;

''(ii) may not order that the importation of the qualifying drug involved cease; and

''(iii) shall promptly notify registered exporters and registered importers.

''(F) DIFFERENCES IN ACTIVE INGREDIENT, ROUTE OF ADMINISTRATION, DOSAGE FORM, OR STRENGTH.—

''(i) IN GENERAL.—A person who manufactures a drug approved under section 505(b) shall submit an application under section 505(b) for approval of another drug that is manufactured for distribution in a permitted country by or for the person that manufactures the drug approved under section 505(b) if—

''(I) there is no qualifying drug in commercial distribution in permitted countries whose combined population represents at least 50 percent of the total population of all permitted countries with the same active ingredient or ingredients, route of administration, dosage form, and strength as the drug approved under section 505(b); and

''(II) each active ingredient of the other drug is related to an active ingredient of the drug approved under section 505(b), as defined in clause (v).

''(ii) APPLICATION UNDER SECTION 505(b).—The application under section 505(b) required under clause (i) shall—

''(I) request approval of the other drug for the indication or indications for which the drug approved under section 505(b) is labeled;

''(II) include the information that the person submitted to the government of the permitted country for purposes of obtaining approval for commercial distribution of the other drug in that country, which if in a language other than English, shall be accompanied by an English translation verified to be complete and accurate, with the name, address, and a brief statement of the qualifications of the person that made the translation;

''(III) include a right of reference to the application for the drug approved under section 505(b); and

''(IV) include such additional information as the Secretary may require.

''(iii) TIMING OF SUBMISSION OF APPLICATION.—An application under section 505(b) required under clause (i) shall be submitted to the Secretary not later than the day on which the information referred to in clause (ii)(II) is submitted to the government of the permitted country.

''(iv) NOTICE OF DECISION ON APPLICATION.—The Secretary shall promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of a determination to approve or to disapprove an application under section 505(b) required under clause (i).

''(v) RELATED ACTIVE INGREDIENTS.—For purposes of clause (i)(II), 2 active ingredients are related if they are—

''(I) the same; or

''(II) different salts, esters, or complexes of the same moiety.

''(3) SECTION 502; LABELING.—

''(A) IMPORTATION BY REGISTERED IMPORTER.—

''(i) IN GENERAL.—In the case of a qualifying drug that is imported or offered for import by a registered importer, such drug shall be considered to be in compliance with section 502 and the labeling requirements under the approved application for the U.S. label drug if the qualifying drug bears—

''(I) a copy of the labeling approved for the U.S. label drug under section 505, without regard to whether the copy bears any trademark involved;

''(II) the name of the manufacturer and location of the manufacturer;

''(III) the lot number assigned by the manufacturer;

''(IV) the name, location, and registration number of the importer; and

''(V) the National Drug Code number assigned to the qualifying drug by the Secretary.

''(ii) REQUEST FOR COPY OF THE LABELING.—The Secretary shall provide such copy to the registered importer involved, upon request of the importer.

''(iii) REQUESTED LABELING.—The labeling provided by the Secretary under clause (ii) shall—

''(I) include the established name, as defined in section 502(e)(3), for each active ingredient in the qualifying drug;

''(II) not include the proprietary name of the U.S. label drug or any active ingredient thereof;

''(III) if required under paragraph (2)(B)(vi)(III), a prominent advisory that the qualifying drug is safe and effective but not bioequivalent to the U.S. label drug; and

''(IV) if the inactive ingredients of the qualifying drug are different from the inactive ingredients for the U.S. label drug, include—

''(aa) a prominent notice that the ingredients of the qualifying drug differ from the ingredients of the U.S. label drug and that the qualifying drug must be dispensed with an advisory to people with allergies about this difference and a list of ingredients; and

''(bb) a list of the ingredients of the qualifying drug as would be required under section 502(e).

''(B) IMPORTATION BY INDIVIDUAL.—

''(i) IN GENERAL.—In the case of a qualifying drug that is imported or offered for import by a registered exporter to an individual, such drug shall be considered to be in compliance with section 502 and the labeling requirements under the approved application for the U.S. label drug if the packaging and labeling of the qualifying drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.) and the labeling of the qualifying drug includes—

''(I) directions for use by the consumer;

''(II) the lot number assigned by the manufacturer;

''(III) the name and registration number of the exporter;

''(IV) if required under paragraph (2)(B)(vi)(III), a prominent advisory that the drug is safe and effective but not bioequivalent to the U.S. label drug;

''(V) if the inactive ingredients of the drug are different from the inactive ingredients for the U.S. label drug—

''(aa) a prominent advisory that persons with an allergy should check the ingredient list of the drug because the ingredients of the drug differ from the ingredients of the U.S. label drug; and

''(bb) a list of the ingredients of the drug as would be required under section 502(e); and

''(VI) a copy of any special labeling that would be required by the Secretary had the U.S. label drug been dispensed by a pharmacist in the United States, without regard to whether the special labeling bears any trademark involved.

''(ii) PACKAGING.—A qualifying drug offered for import to an individual by an exporter under this section that is packaged in a unit-of-use container (as those items are defined in the United States Pharmacopeia and National Formulary) shall not be repackaged, provided that—

''(I) the packaging complies with all applicable regulations under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.); or

''(II) the consumer consents to waive the requirements of such Act, after being informed that the packaging does not comply with such Act and that the exporter will provide the drug in packaging that is compliant at no additional cost.

''(iii) REQUEST FOR COPY OF SPECIAL LABELING AND INGREDIENT LIST.—The Secretary shall provide to the registered exporter involved a copy of the special labeling, the advisory, and the ingredient list described under clause (i), upon request of the exporter.

''(iv) REQUESTED LABELING AND INGREDIENT LIST.—The labeling and ingredient list provided by the Secretary under clause (iii) shall—

''(I) include the established name, as defined in section 502(e)(3), for each active ingredient in the drug; and

''(II) not include the proprietary name of the U.S. label drug or any active ingredient thereof.

''(4) SECTION 501; ADULTERATION.—A qualifying drug that is imported or offered for import under subsection (a) shall be considered to be in compliance with section 501 if the drug is in compliance with subsection (c).

''(5) STANDARDS FOR REFUSING ADMISSION.—A drug exported under subsection (a) from a registered exporter or imported by a registered importer may be refused admission into the United States if 1 or more of the following applies:

''(A) The drug is not a qualifying drug.

''(B) A notice for the drug required under paragraph (2)(B) has not been submitted to the Secretary.

''(C) The Secretary has ordered that importation of the drug from the permitted country cease under paragraph (2) (C) or (D).

''(D) The drug does not comply with paragraph (3) or (4).

''(E) The shipping container appears damaged in a way that may affect the strength, quality, or purity of the drug.

''(F) The Secretary becomes aware that—

''(i) the drug may be counterfeit;

''(ii) the drug may have been prepared, packed, or held under insanitary conditions; or

''(iii) the methods used in, or the facilities or controls used for, the manufacturing, processing, packing, or holding of the drug do not conform to good manufacturing practice.

''(G) The Secretary has obtained an injunction under section 302 that prohibits the distribution of the drug in interstate commerce.

''(H) The Secretary has under section 505(e) withdrawn approval of the drug.

''(I) The manufacturer of the drug has instituted a recall of the drug.

''(J) If the drug is imported or offered for import by a registered importer without submission of a notice in accordance with subsection (d)(4).

''(K) If the drug is imported or offered for import from a registered exporter to an individual and 1 or more of the following applies:

''(i) The shipping container for such drug does not bear the markings required under subsection (d)(2).

''(ii) The markings on the shipping container appear to be counterfeit.

''(iii) The shipping container or markings appear to have been tampered with.

''(h) LICENSING AS PHARMACIST.—A registration condition is that the exporter involved agrees that a qualifying drug will be exported to an individual only if the Secretary has verified that—

''(1) the exporter is authorized under the law of the permitted country in which the exporter is located to dispense prescription drugs; and

''(2) the exporter employs persons that are licensed under the law of the permitted country in which the exporter is located to dispense prescription drugs in sufficient number to dispense safely the drugs exported by the exporter to individuals, and the exporter assigns to those persons responsibility for dispensing such drugs to individuals.

''(i) INDIVIDUALS; CONDITIONS FOR IMPORTATION.—

''(1) IN GENERAL.—For purposes of subsection (a)(2)(B), the importation of a qualifying drug by an individual is in accordance with this subsection if the following conditions are met:

''(A) The drug is accompanied by a copy of a prescription for the drug, which prescription—

''(i) is valid under applicable Federal and State laws; and

''(ii) was issued by a practitioner who, under the law of a State of which the individual is a resident, or in which the individual receives care from the practitioner who issues the prescription, is authorized to administer prescription drugs.

''(B) The drug is accompanied by a copy of the documentation that was required under the law or regulations of the permitted country in which the exporter is located, as a condition of dispensing the drug to the individual.

''(C) The copies referred to in subparagraphs (A)(i) and (B) are marked in a manner sufficient—

''(i) to indicate that the prescription, and the equivalent document in the permitted country in which the exporter is located, have been filled; and

''(ii) to prevent a duplicative filling by another pharmacist.

''(D) The individual has provided to the registered exporter a complete list of all drugs used by the individual for review by the individuals who dispense the drug.

''(E) The quantity of the drug does not exceed a 90-day supply.

''(F) The drug is not an ineligible subpart H drug. For purposes of this section, a prescription drug is an 'ineligible subpart H drug' if the drug was approved by the Secretary under subpart H of part 314 of title 21, Code of Federal Regulations (relating to accelerated approval), with restrictions under section 520 of such part to assure safe use, and the Secretary has published in the Federal Register a notice that the Secretary has determined that good cause exists to prohibit the drug from being imported pursuant to this subsection.

''(2) NOTICE REGARDING DRUG REFUSED ADMISSION.—If a registered exporter ships a drug to an individual pursuant to subsection (a)(2)(B) and the drug is refused admission to the United States, a written notice shall be sent to the individual and to the exporter that informs the individual and the exporter of such refusal and the reason for the refusal.

''(j) MAINTENANCE OF RECORDS AND SAMPLES.—

''(1) IN GENERAL.—A registration condition is that the importer or exporter involved shall—

''(A) maintain records required under this section for not less than 2 years; and

''(B) maintain samples of each lot of a qualifying drug required under this section for not less than 2 years.

''(2) PLACE OF RECORD MAINTENANCE.—The records described under paragraph (1) shall be maintained—

''(A) in the case of an importer, at the place of business of the importer at which the importer initially receives the qualifying drug after importation; or

''(B) in the case of an exporter, at the facility from which the exporter ships the qualifying drug to the United States.

''(k) DRUG RECALLS.—

''(1) MANUFACTURERS.—A person that manufactures a qualifying drug imported from a permitted country under this section shall promptly inform the Secretary—

''(A) if the drug is recalled or withdrawn from the market in a permitted country;

''(B) how the drug may be identified, including lot number; and

''(C) the reason for the recall or withdrawal.

''(2) SECRETARY.—With respect to each permitted country, the Secretary shall—

''(A) enter into an agreement with the government of the country to receive information about recalls and withdrawals of qualifying drugs in the country; or

''(B) monitor recalls and withdrawals of qualifying drugs in the country using any information that is available to the public in any media.

''(3) NOTICE.—The Secretary may notify, as appropriate, registered exporters, registered importers, wholesalers, pharmacies, or the public of a recall or withdrawal of a qualifying drug in a permitted country.

''(l) DRUG LABELING AND PACKAGING.—

''(1) IN GENERAL.—When a qualifying drug that is imported into the United States by an importer under subsection (a) is dispensed by a pharmacist to an individual, the pharmacist shall provide that the packaging and labeling of the drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.) and shall include with any other labeling provided to the individual the following:

''(A) The lot number assigned by the manufacturer.

''(B) The name and registration number of the importer.

''(C) If required under paragraph (2)(B)(vi)(III) of subsection (g), a prominent advisory that the drug is safe and effective but not bioequivalent to the U.S. label drug.

''(D) If the inactive ingredients of the drug are different from the inactive ingredients for the U.S. label drug—

''(i) a prominent advisory that persons with allergies should check the ingredient list of the drug because the ingredients of the drug differ from the ingredients of the U.S. label drug; and

''(ii) a list of the ingredients of the drug as would be required under section 502(e).

''(2) PACKAGING.—A qualifying drug that is packaged in a unit-of-use container (as those terms are defined in the United States Pharmacopeia and National Formulary) shall not be repackaged, provided that—

''(A) the packaging complies with all applicable regulations under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.); or

''(B) the consumer consents to waive the requirements of such Act, after being informed that the packaging does not comply with such Act and that the pharmacist will provide the drug in packaging that is compliant at no additional cost.

''(m) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, this section does not authorize the importation into the United States of a qualifying drug donated or otherwise supplied for free or at nominal cost by the manufacturer of the drug to a charitable or humanitarian organization, including the United Nations and affiliates, or to a government of a foreign country.

''(n) UNFAIR AND DISCRIMINATORY ACTS AND PRACTICES.—

''(1) IN GENERAL.—It is unlawful for a manufacturer, directly or indirectly (including by being a party to a licensing agreement or other agreement), to—

''(A) discriminate by charging a higher price for a prescription drug sold to a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section than the price that is charged, inclusive of rebates or other incentives to the permitted country or other person, to another person that is in the same country and that does not export a qualifying drug into the United States under this section;

''(B) discriminate by charging a higher price for a prescription drug sold to a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section than the price that is charged to another person in the United States that does not import a qualifying drug under this section, or that does not distribute, sell, or use such a drug;

''(C) discriminate by denying, restricting, or delaying supplies of a prescription drug to a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section or to a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section;

''(D) discriminate by publicly, privately, or otherwise refusing to do business with a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section or with a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section;

''(E) knowingly fail to submit a notice under subsection (g)(2)(B)(i), knowingly fail to submit such a notice on or before the date specified in subsection (g)(2)(B)(v) or as otherwise required under subsection (e) (3), (4), and (5) of section ___4 of the Pharmaceutical Market Access and Drug Safety Act of 2006, knowingly submit such a notice that makes a materially false, fictitious, or fraudulent statement, or knowingly fail to provide promptly any information requested by the Secretary to review such a notice;

''(F) knowingly fail to submit an application required under subsection (g)(2)(F), knowingly fail to submit such an application on or before the date specified in subsection (g)(2)(F)(ii), knowingly submit such an application that makes a materially false, fictitious, or fraudulent statement, or knowingly fail to provide promptly any information requested by the Secretary to review such an application;

''(G) cause there to be a difference (including a difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) between a prescription drug for distribution in the United States and the drug for distribution in a permitted country;

''(H) refuse to allow an inspection authorized under this section of an establishment that manufactures a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country;

''(I) fail to conform to the methods used in, or the facilities used for, the manufacturing, processing, packing, or holding of a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country to good manufacturing practice under this Act;

''(J) become a party to a licensing agreement or other agreement related to a qualifying drug that fails to provide for compliance with all requirements of this section with respect to such drug;

''(K) enter into a contract that restricts, prohibits, or delays the importation of a qualifying drug under this section;

''(L) engage in any other action to restrict, prohibit, or delay the importation of a qualifying drug under this section; or

''(M) engage in any other action that the Federal Trade Commission determines to discriminate against a person that engages or attempts to engage in the importation of a qualifying drug under this section.

''(2) REFERRAL OF POTENTIAL VIOLATIONS.—The Secretary shall promptly refer to the Federal Trade Commission each potential violation of subparagraph (E), (F), (G), (H), or (I) of paragraph (1) that becomes known to the Secretary.

''(3) AFFIRMATIVE DEFENSE.—

''(A) DISCRIMINATION.—It shall be an affirmative defense to a charge that a manufacturer has discriminated under subparagraph (A), (B), (C), (D), or (M) of paragraph (1) that the higher price charged for a prescription drug sold to a person, the denial, restriction, or delay of supplies of a prescription drug to a person, the refusal to do business with a person, or other discriminatory activity against a person, is not based, in whole or in part, on—

''(i) the person exporting or importing a qualifying drug into the United States under this section; or

''(ii) the person distributing, selling, or using a qualifying drug imported into the United States under this section.

''(B) DRUG DIFFERENCES.—It shall be an affirmative defense to a charge that a manufacturer has caused there to be a difference described in subparagraph (G) of paragraph (1) that—

''(i) the difference was required by the country in which the drug is distributed;

''(ii) the Secretary has determined that the difference was necessary to improve the safety or effectiveness of the drug;

''(iii) the person manufacturing the drug for distribution in the United States has given notice to the Secretary under subsection (g)(2)(B)(i) that the drug for distribution in the United States is not different from a drug for distribution in permitted countries whose combined population represents at least 50 percent of the total population of all permitted countries; or

''(iv) the difference was not caused, in whole or in part, for the purpose of restricting importation of the drug into the United States under this section.

''(4) EFFECT OF SUBSECTION.—

''(A) SALES IN OTHER COUNTRIES.—This subsection applies only to the sale or distribution of a prescription drug in a country if the manufacturer of the drug chooses to sell or distribute the drug in the country. Nothing in this subsection shall be construed to compel the manufacturer of a drug to distribute or sell the drug in a country.

''(B) DISCOUNTS TO INSURERS, HEALTH PLANS, PHARMACY BENEFIT MANAGERS, AND COVERED ENTITIES.—Nothing in this subsection shall be construed to—

''(i) prevent or restrict a manufacturer of a prescription drug from providing discounts to an insurer, health plan, pharmacy benefit manager in the United States, or covered entity in the drug discount program under section 340B of the Public Health Service Act (42 U.S.C. 256b) in return for inclusion of the drug on a formulary;

''(ii) require that such discounts be made available to other purchasers of the prescription drug; or

''(iii) prevent or restrict any other measures taken by an insurer, health plan, or pharmacy benefit manager to encourage consumption of such prescription drug.

''(C) CHARITABLE CONTRIBUTIONS.—Nothing in this subsection shall be construed to—

''(i) prevent a manufacturer from donating a prescription drug, or supplying a prescription drug at nominal cost, to a charitable or humanitarian organization, including the United Nations and affiliates, or to a government of a foreign country; or

''(ii) apply to such donations or supplying of a prescription drug.

''(5) ENFORCEMENT.—

''(A) UNFAIR OR DECEPTIVE ACT OR PRACTICE.—A violation of this subsection shall be treated as a violation of a rule defining an unfair or deceptive act or practice prescribed under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)).

''(B) ACTIONS BY THE COMMISSION.—The Federal Trade Commission—

''(i) shall enforce this subsection in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this section; and

''(ii) may seek monetary relief threefold the damages sustained, in addition to any other remedy available to the Federal Trade Commission under the Federal Trade Commission Act (15 U.S.C. 41 et seq.).

''(6) ACTIONS BY STATES.—

''(A) IN GENERAL.—

''(i) CIVIL ACTIONS.—In any case in which the attorney general of a State has reason to believe that an interest of the residents of that State have been adversely affected by any manufacturer that violates paragraph (1), the attorney general of a State may bring a civil action on behalf of the residents of the State, and persons doing business in the State, in a district court of the United States of appropriate jurisdiction to—

''(I) enjoin that practice;

''(II) enforce compliance with this subsection;

''(III) obtain damages, restitution, or other compensation on behalf of residents of the State and persons doing business in the State, including threefold the damages; or

''(IV) obtain such other relief as the court may consider to be appropriate.

''(ii) NOTICE.—

''(I) IN GENERAL.—Before filing an action under clause (i), the attorney general of the State involved shall provide to the Federal Trade Commission—

''(aa) written notice of that action; and

''(bb) a copy of the complaint for that action.

''(II) EXEMPTION.—Subclause (I) shall not apply with respect to the filing of an action by an attorney general of a State under this paragraph, if the attorney general determines that it is not feasible to provide the notice described in that subclause before filing of the action. In such case, the attorney general of a State shall provide notice and a copy of the complaint to the Federal Trade Commission at the same time as the attorney general files the action.

''(B) INTERVENTION.—

''(i) IN GENERAL.—On receiving notice under subparagraph (A)(ii), the Federal Trade Commission shall have the right to intervene in the action that is the subject of the notice.

''(ii) EFFECT OF INTERVENTION.—If the Federal Trade Commission intervenes in an action under subparagraph (A), it shall have the right—

''(I) to be heard with respect to any matter that arises in that action; and

''(II) to file a petition for appeal.

''(C) CONSTRUCTION.—For purposes of bringing any civil action under subparagraph (A), nothing in this subsection shall be construed to prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of that State to—

''(i) conduct investigations;

''(ii) administer oaths or affirmations; or

''(iii) compel the attendance of witnesses or the production of documentary and other evidence.

''(D) ACTIONS BY THE COMMISSION.—In any case in which an action is instituted by or on behalf of the Federal Trade Commission for a violation of paragraph (1), a State may not, during the pendency of that action, institute an action under subparagraph (A) for the same violation against any defendant named in the complaint in that action.

''(E) VENUE.—Any action brought under subparagraph (A) may be brought in the district court of the United States that meets applicable requirements relating to venue under section 1391 of title 28, United States Code.

''(F) SERVICE OF PROCESS.—In an action brought under subparagraph (A), process may be served in any district in which the defendant—

''(i) is an inhabitant; or

''(ii) may be found.

''(G) MEASUREMENT OF DAMAGES.—In any action under this paragraph to enforce a cause of action under this subsection in which there has been a determination that a defendant has violated a provision of this subsection, damages may be proved and assessed in the aggregate by statistical or sampling methods, by the computation of illegal overcharges or by such other reasonable system of estimating aggregate damages as the court in its discretion may permit without the necessity of separately proving the individual claim of, or amount of damage to, persons on whose behalf the suit was brought.

''(H) EXCLUSION ON DUPLICATIVE RELIEF.—The district court shall exclude from the amount of monetary relief awarded in an action under this paragraph brought by the attorney general of a State any amount of monetary relief which duplicates amounts which have been awarded for the same injury.

''(7) EFFECT ON ANTITRUST LAWS.—Nothing in this subsection shall be construed to modify, impair, or supersede the operation of the antitrust laws. For the purpose of this subsection, the term 'antitrust laws' has the meaning given it in the first section of the Clayton Act, except that it includes section 5 of the Federal Trade Commission Act to the extent that such section 5 applies to unfair methods of competition.

''(8) MANUFACTURER.—In this subsection, the term 'manufacturer' means any entity, including any affiliate or licensee of that entity, that is engaged in—

''(A) the production, preparation, propagation, compounding, conversion, or processing of a prescription drug, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

''(B) the packaging, repackaging, labeling, relabeling, or distribution of a prescription drug.''.

(b) PROHIBITED ACTS.—The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 301 (21 U.S.C. 331), by striking paragraph (aa) and inserting the following:

''(aa)(1) The sale or trade by a pharmacist, or by a business organization of which the pharmacist is a part, of a qualifying drug that under section 804(a)(2)(A) was imported by the pharmacist, other than—

''(A) a sale at retail made pursuant to dispensing the drug to a customer of the pharmacist or organization; or

''(B) a sale or trade of the drug to a pharmacy or a wholesaler registered to import drugs under section 804.

''(2) The sale or trade by an individual of a qualifying drug that under section 804(a)(2)(B) was imported by the individual.

''(3) The making of a materially false, fictitious, or fraudulent statement or representation, or a material omission, in a notice under clause (i) of section 804(g)(2)(B) or in an application required under section 804(g)(2)(F), or the failure to submit such a notice or application.

''(4) The importation of a drug in violation of a registration condition or other requirement under section 804, the falsification of any record required to be maintained, or provided to the Secretary, under such section, or the violation of any registration condition or other requirement under such section.''; and

(2) in section 303(a) (21 U.S.C. 333(a)), by striking paragraph (6) and inserting the following:

''(6) Notwithstanding subsection (a), any person that knowingly violates section 301(i)(2) or (3) or section 301(aa)(4) shall be imprisoned not more than 10 years, or fined in accordance with title 18, United States Code, or both.''.

(c) AMENDMENT OF CERTAIN PROVISIONS.—

(1) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by striking subsection (g) and inserting the following:

''(g) With respect to a prescription drug that is imported or offered for import into the United States by an individual who is not in the business of such importation, that is not shipped by a registered exporter under section 804, and that is refused admission under subsection (a), the Secretary shall notify the individual that—

''(1) the drug has been refused admission because the drug was not a lawful import under section 804;

''(2) the drug is not otherwise subject to a waiver of the requirements of subsection (a);

''(3) the individual may under section 804 lawfully import certain prescription drugs from exporters registered with the Secretary under section 804; and

''(4) the individual can find information about such importation, including a list of registered exporters, on the Internet website of the Food and Drug Administration or through a toll-free telephone number required under section 804.''.

(2) ESTABLISHMENT REGISTRATION.—Section 510(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)) is amended in paragraph (1) by inserting after ''import into the United States'' the following: '', including a drug that is, or may be, imported or offered for import into the United States under section 804,''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date that is 90 days after the date of enactment of this title.

(d) EXHAUSTION.—

(1) IN GENERAL.—Section 271 of title 35, United States Code, is amended—

(A) by redesignating subsections (h) and (i) as (i) and (j), respectively; and

(B) by inserting after subsection (g) the following:

''(h) It shall not be an act of infringement to use, offer to sell, or sell within the United States or to import into the United States any patented invention under section 804 of the Federal Food, Drug, and Cosmetic Act that was first sold abroad by or under authority of the owner or licensee of such patent.''.

(2) RULE OF CONSTRUCTION.—Nothing in the amendment made by paragraph (1) shall be construed to affect the ability of a patent owner or licensee to enforce their patent, subject to such amendment.

(e) EFFECT OF SECTION 804.—

(1) IN GENERAL.—Section 804 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall permit the importation of qualifying drugs (as defined in such section 804) into the United States without regard to the status of the issuance of implementing regulations—

(A) from exporters registered under such section 804 on the date that is 90 days after the date of enactment of this title; and

(B) from permitted countries, as defined in such section 804, by importers registered under such section 804 on the date that is 1 year after the date of enactment of this title.

(2) REVIEW OF REGISTRATION BY CERTAIN EXPORTERS.—

(A) REVIEW PRIORITY.—In the review of registrations submitted under subsection (b) of

such section 804, registrations submitted by entities in Canada that are significant exporters of prescription drugs to individuals in the United States as of the date of enactment of this title will have priority during the 90 day period that begins on such date of enactment.

(B) PERIOD FOR REVIEW.—During such 90-day period, the reference in subsection (b)(2)(A) of such section 804 to 90 days (relating to approval or disapproval of registrations) is, as applied to such entities, deemed to be 30 days.

(C) LIMITATION.—That an exporter in Canada exports, or has exported, prescription drugs to individuals in the United States on or before the date that is 90 days after the date of enactment of this title shall not serve as a basis, in whole or in part, for disapproving a registration under such section 804 from the exporter.

(D) FIRST YEAR LIMIT ON NUMBER OF EXPORTERS.—During the 1-year period beginning on the date of enactment of this title, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') may limit the number of registered exporters under such section 804 to not less than 50, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(E) SECOND YEAR LIMIT ON NUMBER OF EXPORTERS.—During the 1-year period beginning on the date that is 1 year after the date of enactment of this title, the Secretary may limit the number of registered exporters under such section 804 to not less than 100, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(F) FURTHER LIMIT ON NUMBER OF EXPORTERS.—During any 1-year period beginning on a date that is 2 or more years after the date of enactment of this title, the Secretary may limit the number of registered exporters under such section 804 to not less than 25 more than the number of such exporters during the previous 1-year period, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(3) LIMITS ON NUMBER OF IMPORTERS.—

(A) FIRST YEAR LIMIT ON NUMBER OF IMPORTERS.—During the 1-year period beginning on the date that is 1 year after the date of enactment of this title, the Secretary may limit the number of registered importers under such section 804 to not less than 100 (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups), so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs imported into the United States.

(B) SECOND YEAR LIMIT ON NUMBER OF IMPORTERS.—During the 1-year period beginning on the date that is 2 years after the date of enactment of this title, the Secretary may limit the number of registered importers under such section 804 to not less than 200 (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups), so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs into the United States.

(C) FURTHER LIMIT ON NUMBER OF IMPORTERS.—During any 1-year period beginning on a date that is 3 or more years after the date of enactment of this title, the Secretary may limit the number of registered importers under such section 804 to not less than 50 more (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups) than the number of such importers during the previous 1-year period, so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs to the United States.

(4) NOTICES FOR DRUGS FOR IMPORT FROM CANADA.—The notice with respect to a qualifying drug introduced for commercial distribution in Canada as of the date of enactment of this title that is required under subsection (g)(2)(B)(i) of such section 804 shall be submitted to the Secretary not later than 30 days after the date of enactment of this title if—

(A) the U.S. label drug (as defined in such section 804) for the qualifying drug is 1 of the 100 prescription drugs with the highest dollar volume of sales in the United States based on the 12 calendar month period most recently completed before the date of enactment of this title; or

(B) the notice is a notice under subsection (g)(2)(B)(i)(II) of such section 804.

(5) NOTICE FOR DRUGS FOR IMPORT FROM OTHER COUNTRIES.—The notice with respect to a qualifying drug introduced for commercial distribution in a permitted country other than Canada as of the date of enactment of this title that is required under subsection (g)(2)(B)(i) of such section 804 shall be submitted to the Secretary not later than 180 days after the date of enactment of this title if—

(A) the U.S. label drug for the qualifying drug is 1 of the 100 prescription drugs with the highest dollar volume of sales in the United States based on the 12 calendar month period that is first completed on the date that is 120 days after the date of enactment of this title; or

(B) the notice is a notice under subsection (g)(2)(B)(i)(II) of such section 804.

(6) NOTICE FOR OTHER DRUGS FOR IMPORT.—

(A) GUIDANCE ON SUBMISSION DATES.—The Secretary shall by guidance establish a series of submission dates for the notices under subsection (g)(2)(B)(i) of such section 804 with respect to qualifying drugs introduced for commercial distribution as of the date of enactment of this title and that are not required to be submitted under paragraph (4) or (5).

(B) CONSISTENT AND EFFICIENT USE OF RESOURCES.—The Secretary shall establish the dates described under subparagraph (A) so that such notices described under subparagraph (A) are submitted and reviewed at a rate that allows consistent and efficient use of the resources and staff available to the Secretary for such reviews. The Secretary may condition the requirement to submit such a notice, and the review of such a notice, on the submission by a registered exporter or a registered importer to the Secretary of a notice that such exporter or importer intends to import such qualifying drug to the United States under such section 804.

(C) PRIORITY FOR DRUGS WITH HIGHER SALES.—The Secretary shall establish the dates described under subparagraph (A) so that the Secretary reviews the notices described under such subparagraph with respect to qualifying drugs with higher dollar volume of sales in the United States before the notices with respect to drugs with lower sales in the United States.

(7) NOTICES FOR DRUGS APPROVED AFTER EFFECTIVE DATE.—The notice required under subsection (g)(2)(B)(i) of such section 804 for a qualifying drug first introduced for commercial distribution in a permitted country (as defined in such section 804) after the date of enactment of this title shall be submitted to and reviewed by the Secretary as provided under subsection (g)(2)(B) of such section 804, without regard to paragraph (4), (5), or (6).

(8) REPORT.—Beginning with the first full fiscal year after the date of enactment of this title, not later than 90 days after the end of each fiscal year during which the Secretary reviews a notice referred to in paragraph (4), (5), or (6), the Secretary shall submit a report to Congress concerning the progress of the Food and Drug Administration in reviewing the notices referred to in paragraphs (4), (5), and (6).

(9) USER FEES.—

(A) EXPORTERS.—When establishing an aggregate total of fees to be collected from exporters under subsection (f)(2) of such section 804, the Secretary shall, under subsection (f)(3)(C)(i) of such section 804, estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered exporters during the first fiscal year in which this title takes effect to be an amount equal to the amount which bears the same ratio to $1,000,000,000 as the number of days in such fiscal year during which this title is effective bears to 365.

(B) IMPORTERS.—When establishing an aggregate total of fees to be collected from importers under subsection (e)(2) of such section 804, the Secretary shall, under subsection (e)(3)(C)(i) of such section 804, estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered importers during—

(i) the first fiscal year in which this title takes effect to be an amount equal to the amount which bears the same ratio to $1,000,000,000 as the number of days in such fiscal year during which this title is effective bears to 365; and

(ii) the second fiscal year in which this title is in effect to be $3,000,000,000.

(C) SECOND YEAR ADJUSTMENT.—

(i) REPORTS.—Not later than February 20 of the second fiscal year in which this title is in effect, registered importers shall report to the Secretary the total price and the total volume of drugs imported to the United States by the importer during the 4-month period from October 1 through January 31 of such fiscal year.

(ii) REESTIMATE.—Notwithstanding subsection (e)(3)(C)(ii) of such section 804 or subparagraph (B), the Secretary shall reestimate the total price of qualifying drugs imported under subsection (a) of such section 804 into the United States by registered importers during the second fiscal year in which this title is in effect. Such reestimate shall be equal to—

(I) the total price of qualifying drugs imported by each importer as reported under clause (i); multiplied by

(II) 3.

(iii) ADJUSTMENT.—The Secretary shall adjust the fee due on April 1 of the second fiscal year in which this title is in effect, from each importer so that the aggregate total of fees collected under subsection (e)(2) for such fiscal year does not exceed the total price of qualifying drugs imported under subsection (a) of such section 804 into the United States by registered importers during such fiscal year as reestimated under clause (ii).

(D) FAILURE TO PAY FEES.—Notwithstanding any other provision of this section, the Secretary may prohibit a registered importer or exporter that is required to pay user fees under subsection (e) or (f) of such section 804 and that fails to pay such fees within 30 days after the date on which it is due, from importing or offering for importation a qualifying drug under such section 804 until such fee is paid.

(E) ANNUAL REPORT.—

(i) FOOD AND DRUG ADMINISTRATION.—Not later than 180 days after the end of each fiscal year during which fees are collected under subsection (e), (f), or (g)(2)(B)(iv) of such section 804, the Secretary shall prepare and submit to the House of Representatives and the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for the fiscal year for which the report is made and credited to the Food and Drug Administration.

(ii) CUSTOMS AND BORDER CONTROL.—Not later than 180 days after the end of each fiscal year during which fees are collected under subsection (e) or (f) of such section 804, the Secretary of Homeland Security, in consultation with the Secretary of the Treasury, shall prepare and submit to the House of Representatives and the Senate a report on the use, by the Bureau of Customs and Border Protection, of the fees, if any, transferred by the Secretary to the Bureau of Customs and Border Protection for the fiscal year for which the report is made.

(10) SPECIAL RULE REGARDING IMPORTATION BY INDIVIDUALS.—

(A) IN GENERAL.—Notwithstanding any provision of this title (or an amendment made by this title), the Secretary shall expedite the designation of any additional countries from which an individual may import a qualifying drug into the United States under such section 804 if any action implemented by the Government of Canada has the effect of limiting or prohibiting the importation of qualifying drugs into the United States from Canada.

(B) TIMING AND CRITERIA.—The Secretary shall designate such additional countries under subparagraph (A)—

(i) not later than 6 months after the date of the action by the Government of Canada described under such subparagraph; and

(ii) using the criteria described under subsection (a)(4)(D)(i)(II) of such section 804.

(f) IMPLEMENTATION OF SECTION 804.—

(1) INTERIM RULE.—The Secretary may promulgate an interim rule for implementing section 804 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a) of this section.

(2) NO NOTICE OF PROPOSED RULEMAKING.—The interim rule described under paragraph (1) may be developed and promulgated by the Secretary without providing general notice of proposed rulemaking.

(3) FINAL RULE.—Not later than 1 year after the date on which the Secretary promulgates an interim rule under paragraph (1), the Secretary shall, in accordance with procedures under section 553 of title 5, United States Code, promulgate a final rule for implementing such section 804, which may incorporate by reference provisions of the interim rule provided for under paragraph (1), to the extent that such provisions are not modified.

(g) CONSUMER EDUCATION.—The Secretary shall carry out activities that educate consumers—

(1) with regard to the availability of qualifying drugs for import for personal use from an exporter registered with and approved by the Food and Drug Administration under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by this section, including information on how to verify whether an exporter is registered and approved by use of the Internet website of the Food and Drug Administration and the toll-free telephone number required by this title;

(2) that drugs that consumers attempt to import from an exporter that is not registered with and approved by the Food and Drug Administration can be seized by the United States Customs Service and destroyed, and that such drugs may be counterfeit, unapproved, unsafe, or ineffective;

(3) with regard to the suspension and termination of any registration of a registered importer or exporter under such section 804; and

(4) with regard to the availability at domestic retail pharmacies of qualifying drugs imported under such section 804 by domestic wholesalers and pharmacies registered with and approved by the Food and Drug Administration.

(h) EFFECT ON ADMINISTRATION PRACTICES.—Notwithstanding any provision of this title (and the amendments made by this title), nothing in this title (or the amendments made by this title) shall be construed to change, limit, or restrict the practices of the Food and Drug Administration or the Bureau of Customs and Border Protection in effect on January 1, 2004, with respect to the importation of prescription drugs into the United States by an individual, on the person of such individual, for personal use.

(i) REPORT TO CONGRESS.—The Federal Trade Commission shall, on an annual basis, submit to Congress a report that describes any action taken during the period for which the report is being prepared to enforce the provisions of section 804(n) of the Federal Food, Drug, and Cosmetic Act (as added by this title), including any pending investigations or civil actions under such section.

SEC. ___5. DISPOSITION OF CERTAIN DRUGS DENIED ADMISSION INTO UNITED STATES.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.), as amended by section ___3, is further amended by adding at the end the following section:

"SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED ADMISSION.

''(a) IN GENERAL.—The Secretary of Homeland Security shall deliver to the Secretary a shipment of drugs that is imported or offered for import into the United States if—

''(1) the shipment has a declared value of less than $10,000; and

''(2)(A) the shipping container for such drugs does not bear the markings required under section 804(d)(2); or

''(B) the Secretary has requested delivery of such shipment of drugs.

''(b) NO BOND OR EXPORT.—Section 801(b) does not authorize the delivery to the owner or consignee of drugs delivered to the Secretary under subsection (a) pursuant to the execution of a bond, and such drugs may not be exported.

''(c) DESTRUCTION OF VIOLATIVE SHIPMENT.—The Secretary shall destroy a shipment of drugs delivered by the Secretary of Homeland Security to the Secretary under subsection (a) if—

''(1) in the case of drugs that are imported or offered for import from a registered exporter under section 804, the drugs are in violation of any standard described in section 804(g)(5); or

''(2) in the case of drugs that are not imported or offered for import from a registered exporter under section 804, the drugs are in violation of a standard referred to in section 801(a) or 801(d)(1).

''(d) CERTAIN PROCEDURES.—

''(1) IN GENERAL.—The delivery and destruction of drugs under this section may be carried out without notice to the importer, owner, or consignee of the drugs except as required by section 801(g) or section 804(i)(2). The issuance of receipts for the drugs, and recordkeeping activities regarding the drugs, may be carried out on a summary basis.

''(2) OBJECTIVE OF PROCEDURES.—Procedures promulgated under paragraph (1) shall be designed toward the objective of ensuring that, with respect to efficiently utilizing Federal resources available for carrying out this section, a substantial majority of shipments of drugs subject to described in subsection (c) are identified and destroyed.

''(e) EVIDENCE EXCEPTION.—Drugs may not be destroyed under subsection (c) to the extent that the Attorney General of the United States determines that the drugs should be preserved as evidence or potential evidence with respect to an offense against the United States.

''(f) RULE OF CONSTRUCTION.—This section may not be construed as having any legal effect on applicable law with respect to a shipment of drugs that is imported or offered for import into the United States and has a declared value equal to or greater than $10,000.''.

(b) PROCEDURES.—Procedures for carrying out section 805 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall be established not later than 90 days after the date of the enactment of this title.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date that is 90 days after the date of enactment of this title.

SEC. ___6. WHOLESALE DISTRIBUTION OF DRUGS; STATEMENTS REGARDING PRIOR SALE, PURCHASE, OR TRADE.

(a) STRIKING OF EXEMPTIONS; APPLICABILITY TO REGISTERED EXPORTERS.—Section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended—

(1) in paragraph (1)—

(A) by striking ''and who is not the manufacturer or an authorized distributor of record of such drug'';

(B) by striking ''to an authorized distributor of record or''; and

(C) by striking subparagraph (B) and inserting the following:

''(B) The fact that a drug subject to subsection (b) is exported from the United States does not with respect to such drug exempt any person that is engaged in the business of the wholesale distribution of the drug from providing the statement described in subparagraph (A) to the person that receives the drug pursuant to the export of the drug.

''(C)(i) The Secretary shall by regulation establish requirements that supersede subparagraph (A) (referred to in this subparagraph as 'alternative requirements') to identify the chain of custody of a drug subject to subsection (b) from the manufacturer of the drug throughout the wholesale distribution of the drug to a pharmacist who intends to sell the drug at retail if the Secretary determines that the alternative requirements, which may include standardized anti-counterfeiting or track-and-trace technologies, will identify such chain of custody or the identity of the discrete package of the drug from which the drug is dispensed with equal or greater certainty to the requirements of subparagraph (A), and that the alternative requirements are economically and technically feasible.

''(ii) When the Secretary promulgates a final rule to establish such alternative requirements, the final rule in addition shall, with respect to the registration condition established in clause (i) of section 804(c)(3)(B), establish a condition equivalent to the alternative requirements, and such equivalent condition may be met in lieu of the registration condition established in such clause (i).'';

(2) in paragraph (2)(A), by adding at the end the following: ''The preceding sentence may not be construed as having any applicability with respect to a registered exporter under section 804.''; and

(3) in paragraph (3), by striking ''and subsection (d)—'' in the matter preceding subparagraph (A) and all that follows through

''the term 'wholesale distribution' means'' in subparagraph (B) and inserting the following: ''and subsection (d), the term 'wholesale distribution' means''.

(b) CONFORMING AMENDMENT.—Section 503(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(d)) is amended by adding at the end the following:

''(4) Each manufacturer of a drug subject to subsection (b) shall maintain at its corporate offices a current list of the authorized distributors of record of such drug.

''(5) For purposes of this subsection, the term 'authorized distributors of record' means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.''.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) shall take effect on January 1, 2010.

(2) DRUGS IMPORTED BY REGISTERED IMPORTERS UNDER SECTION 804.—Notwithstanding paragraph (1), the amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) shall take effect on the date that is 90 days after the date of enactment of this title with respect to qualifying drugs imported under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by section ___4.

(3) HIGH-RISK DRUGS.—

(A) IN GENERAL.—Notwithstanding paragraph (1), the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') may apply the amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) before January 1, 2010, with respect to a prescription drug if the Secretary—

(i) determines that the drug is at high risk for being counterfeited; and

(ii) publishes the determination and the basis for the determination in the Federal Register.

(B) PEDIGREE NOT REQUIRED.—Notwithstanding a determination under subparagraph (A) with respect to a prescription drug, the amendments described in such subparagraph shall not apply with respect to a wholesale distribution of such drug if the drug is distributed by the manufacturer of the drug to a person that distributes the drug to a retail pharmacy for distribution to the consumer or patient, with no other intervening transactions.

(C) LIMITATION.—The Secretary may make the determination under subparagraph (A) with respect to not more than 50 drugs before January 1, 2010.

(4) EFFECT WITH RESPECT TO REGISTERED EXPORTERS.—The amendment made by subsection (a)(2) shall take effect on the date that is 90 days after the date of enactment of this title.

(5) ALTERNATIVE REQUIREMENTS.—The Secretary shall issue regulations to establish the alternative requirements, referred to in the amendment made by subsection (a)(1), that take effect not later than—

(A) January 1, 2008, with respect to a prescription drug determined under paragraph (3)(A) to be at high risk for being counterfeited; and

(B) January 1, 2010, with respect to all other prescription drugs.

(6) INTERMEDIATE REQUIREMENTS.—With respect to the prescription drugs described under paragraph (5)(B), the Secretary shall by regulation require the use of standardized anti-counterfeiting or track-and-trace technologies on such prescription drugs at the case and pallet level effective not later than January 1, 2008.

(7) ADDITIONAL REQUIREMENTS.—

(A) IN GENERAL.—Notwithstanding any other provision of this section, the Secretary shall, not later than January 1, 2007, require that the packaging of any prescription drug incorporates—

(i) overt optically variable counterfeit-resistant technologies that—

(I) are visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices, or scanners;

(II) are similar to that used by the Bureau of Engraving and Printing to secure United States currency;

(III) are manufactured and distributed in a highly secure, tightly controlled environment; and

(IV) incorporate additional layers of nonvisible convert security features up to and including forensic capability, as described in subparagraph (B); or

(ii) technologies that have a function of security comparable to that described in clause (i), as determined by the Secretary.

(B) STANDARDS FOR PACKAGING.—For the purpose of making it more difficult to counterfeit the packaging of drugs subject to this paragraph, the manufacturers of such drugs shall incorporate the technologies described in subparagraph (A) into at least 1 additional element of the physical packaging of the drugs, including blister packs, shrink wrap, package labels, package seals, bottles, and boxes.

SEC. ___7. INTERNET SALES OF PRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503A the following:

''SEC. 503B. INTERNET SALES OF PRESCRIPTION DRUGS.

''(a) REQUIREMENTS REGARDING INFORMATION ON INTERNET SITE.—

''(1) IN GENERAL.—A person may not dispense a prescription drug pursuant to a sale of the drug by such person if—

''(A) the purchaser of the drug submitted the purchase order for the drug, or conducted any other part of the sales transaction for the drug, through an Internet site;

''(B) the person dispenses the drug to the purchaser by mailing or shipping the drug to the purchaser; and

''(C) such site, or any other Internet site used by such person for purposes of sales of a prescription drug, fails to meet each of the requirements specified in paragraph (2), other than a site or pages on a site that—

''(i) are not intended to be accessed by purchasers or prospective purchasers; or

''(ii) provide an Internet information location tool within the meaning of section 231(e)(5) of the Communications Act of 1934 (47 U.S.C. 231(e)(5)).

''(2) REQUIREMENTS.—With respect to an Internet site, the requirements referred to in subparagraph (C) of paragraph (1) for a person to whom such paragraph applies are as follows:

''(A) Each page of the site shall include either the following information or a link to a page that provides the following information:

''(i) The name of such person.

''(ii) Each State in which the person is authorized by law to dispense prescription drugs.

''(iii) The address and telephone number of each place of business of the person with respect to sales of prescription drugs through the Internet, other than a place of business that does not mail or ship prescription drugs to purchasers.

''(iv) The name of each individual who serves as a pharmacist for prescription drugs that are mailed or shipped pursuant to the site, and each State in which the individual is authorized by law to dispense prescription drugs.

''(v) If the person provides for medical consultations through the site for purposes of providing prescriptions, the name of each individual who provides such consultations; each State in which the individual is licensed or otherwise authorized by law to provide such consultations or practice medicine; and the type or types of health professions for which the individual holds such licenses or other authorizations.

''(B) A link to which paragraph (1) applies shall be displayed in a clear and prominent place and manner, and shall include in the caption for the link the words 'licensing and contact information'.

''(b) INTERNET SALES WITHOUT APPROPRIATE MEDICAL RELATIONSHIPS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), a person may not dispense a prescription drug, or sell such a drug, if—

''(A) for purposes of such dispensing or sale, the purchaser communicated with the person through the Internet;

''(B) the patient for whom the drug was dispensed or purchased did not, when such communications began, have a prescription for the drug that is valid in the United States;

''(C) pursuant to such communications, the person provided for the involvement of a practitioner, or an individual represented by the person as a practitioner, and the practitioner or such individual issued a prescription for the drug that was purchased;

''(D) the person knew, or had reason to know, that the practitioner or the individual referred to in subparagraph (C) did not, when issuing the prescription, have a qualifying medical relationship with the patient; and

''(E) the person received payment for the dispensing or sale of the drug.

For purposes of subparagraph (E), payment is received if money or other valuable consideration is received.

''(2) EXCEPTIONS.—Paragraph (1) does not apply to—

''(A) the dispensing or selling of a prescription drug pursuant to telemedicine practices sponsored by—

''(i) a hospital that has in effect a provider agreement under title XVIII of the Social Security Act (relating to the Medicare program); or

''(ii) a group practice that has not fewer than 100 physicians who have in effect provider agreements under such title; or

''(B) the dispensing or selling of a prescription drug pursuant to practices that promote the public health, as determined by the Secretary by regulation.

''(3) QUALIFYING MEDICAL RELATIONSHIP.—

''(A) IN GENERAL.—With respect to issuing a prescription for a drug for a patient, a practitioner has a qualifying medical relationship with the patient for purposes of this section if—

''(i) at least one in-person medical evaluation of the patient has been conducted by the practitioner; or

''(ii) the practitioner conducts a medical evaluation of the patient as a covering practitioner.

''(B) IN-PERSON MEDICAL EVALUATION.—A medical evaluation by a practitioner is an in-person medical evaluation for purposes of this section if the practitioner is in the physical presence of the patient as part of conducting the evaluation, without regard to whether portions of the evaluation are conducted by other health professionals.

''(C) COVERING PRACTITIONER.—With respect to a patient, a practitioner is a covering practitioner for purposes of this section if

the practitioner conducts a medical evaluation of the patient at the request of a practitioner who has conducted at least one in-person medical evaluation of the patient and is temporarily unavailable to conduct the evaluation of the patient. A practitioner is a covering practitioner without regard to whether the practitioner has conducted any in-person medical evaluation of the patient involved.

''(4) RULES OF CONSTRUCTION.—

''(A) INDIVIDUALS REPRESENTED AS PRACTITIONERS.—A person who is not a practitioner (as defined in subsection (e)(1)) lacks legal capacity under this section to have a qualifying medical relationship with any patient.

''(B) STANDARD PRACTICE OF PHARMACY.—Paragraph (1) may not be construed as prohibiting any conduct that is a standard practice in the practice of pharmacy.

''(C) APPLICABILITY OF REQUIREMENTS.—Paragraph (3) may not be construed as having any applicability beyond this section, and does not affect any State law, or interpretation of State law, concerning the practice of medicine.

''(c) ACTIONS BY STATES.—

''(1) IN GENERAL.—Whenever an attorney general of any State has reason to believe that the interests of the residents of that State have been or are being threatened or adversely affected because any person has engaged or is engaging in a pattern or practice that violates section 301(l), the State may bring a civil action on behalf of its residents in an appropriate district court of the United States to enjoin such practice, to enforce compliance with such section (including a nationwide injunction), to obtain damages, restitution, or other compensation on behalf of residents of such State, to obtain reasonable attorneys fees and costs if the State prevails in the civil action, or to obtain such further and other relief as the court may deem appropriate.

''(2) NOTICE.—The State shall serve prior written notice of any civil action under paragraph (1) or (5)(B) upon the Secretary and provide the Secretary with a copy of its complaint, except that if it is not feasible for the State to provide such prior notice, the State shall serve such notice immediately upon instituting such action. Upon receiving a notice respecting a civil action, the Secretary shall have the right—

''(A) to intervene in such action;

''(B) upon so intervening, to be heard on all matters arising therein; and

''(C) to file petitions for appeal.

''(3) CONSTRUCTION.—For purposes of bringing any civil action under paragraph (1), nothing in this chapter shall prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of such State to conduct investigations or to administer oaths or affirmations or to compel the attendance of witnesses or the production of documentary and other evidence.

''(4) VENUE; SERVICE OF PROCESS.—Any civil action brought under paragraph (1) in a district court of the United States may be brought in the district in which the defendant is found, is an inhabitant, or transacts business or wherever venue is proper under section 1391 of title 28, United States Code. Process in such an action may be served in any district in which the defendant is an inhabitant or in which the defendant may be found.

''(5) ACTIONS BY OTHER STATE OFFICIALS.—

''(A) Nothing contained in this section shall prohibit an authorized State official from proceeding in State court on the basis of an alleged violation of any civil or criminal statute of such State.

''(B) In addition to actions brought by an attorney general of a State under paragraph (1), such an action may be brought by officers of such State who are authorized by the State to bring actions in such State on behalf of its residents.

''(d) EFFECT OF SECTION.—This section shall not apply to a person that is a registered exporter under section 804.

''(e) GENERAL DEFINITIONS.—For purposes of this section:

''(1) The term 'practitioner' means a practitioner referred to in section 503(b)(1) with respect to issuing a written or oral prescription.

''(2) The term 'prescription drug' means a drug that is described in section 503(b)(1).

''(3) The term 'qualifying medical relationship', with respect to a practitioner and a patient, has the meaning indicated for such term in subsection (b).

''(f) INTERNET-RELATED DEFINITIONS.—

''(1) IN GENERAL.—For purposes of this section:

''(A) The term 'Internet' means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected world-wide network of networks that employ the transmission control protocol/internet protocol, or any predecessor or successor protocols to such protocol, to communicate information of all kinds by wire or radio.

''(B) The term 'link', with respect to the Internet, means one or more letters, words, numbers, symbols, or graphic items that appear on a page of an Internet site for the purpose of serving, when activated, as a method for executing an electronic command—

''(i) to move from viewing one portion of a page on such site to another portion of the page;

''(ii) to move from viewing one page on such site to another page on such site; or

''(iii) to move from viewing a page on one Internet site to a page on another Internet site.

''(C) The term 'page', with respect to the Internet, means a document or other file accessed at an Internet site.

''(D)(i) The terms 'site' and 'address', with respect to the Internet, mean a specific location on the Internet that is determined by Internet Protocol numbers. Such term includes the domain name, if any.

''(ii) The term 'domain name' means a method of representing an Internet address without direct reference to the Internet Protocol numbers for the address, including methods that use designations such as '.com', '.edu', '.gov', '.net', or '.org'.

''(iii) The term 'Internet Protocol numbers' includes any successor protocol for determining a specific location on the Internet.

''(2) AUTHORITY OF SECRETARY.—The Secretary may by regulation modify any definition under paragraph (1) to take into account changes in technology.

''(g) INTERACTIVE COMPUTER SERVICE; ADVERTISING.—No provider of an interactive computer service, as defined in section 230(f)(2) of the Communications Act of 1934 (47 U.S.C. 230(f)(2)), or of advertising services shall be liable under this section for dispensing or selling prescription drugs in violation of this section on account of another person's selling or dispensing such drugs, provided that the provider of the interactive computer service or of advertising services does not own or exercise corporate control over such person.''.

(b) INCLUSION AS PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by inserting after paragraph (k) the following:

''(l) The dispensing or selling of a prescription drug in violation of section 503B.''.

(c) INTERNET SALES OF PRESCRIPTION DRUGS; CONSIDERATION BY SECRETARY OF PRACTICES AND PROCEDURES FOR CERTIFICATION OF LEGITIMATE BUSINESSES.—In carrying out section 503B of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section), the Secretary of Health and Human Services shall take into consideration the practices and procedures of public or private entities that certify that businesses selling prescription drugs through Internet sites are legitimate businesses, including practices and procedures regarding disclosure formats and verification programs.

(d) REPORTS REGARDING INTERNET-RELATED VIOLATIONS OF FEDERAL AND STATE LAWS ON DISPENSING OF DRUGS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall, pursuant to the submission of an application meeting the criteria of the Secretary, make an award of a grant or contract to the National Clearinghouse on Internet Prescribing (operated by the Federation of State Medical Boards) for the purpose of—

(A) identifying Internet sites that appear to be in violation of Federal or State laws concerning the dispensing of drugs;

(B) reporting such sites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General and the Secretary, for further investigation; and

(C) submitting, for each fiscal year for which the award under this subsection is made, a report to the Secretary describing investigations undertaken with respect to violations described in subparagraph (A).

(2) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out paragraph (1), there is authorized to be appropriated $100,000 for each of the first 3 fiscal years in which this section is in effect.

(e) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) take effect 90 days after the date of enactment of this title, without regard to whether a final rule to implement such amendments has been promulgated by the Secretary of Health and Human Services under section 701(a) of the Federal Food, Drug, and Cosmetic Act. The preceding sentence may not be construed as affecting the authority of such Secretary to promulgate such a final rule.

SEC. ___8. PROHIBITING PAYMENTS TO UNREGISTERED FOREIGN PHARMACIES.

(a) IN GENERAL.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(g) RESTRICTED TRANSACTIONS.—

''(1) IN GENERAL.—The introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system is prohibited.

''(2) PAYMENT SYSTEM.—

''(A) IN GENERAL.—The term 'payment system' means a system used by a person described in subparagraph (B) to effect a credit transaction, electronic fund transfer, or money transmitting service that may be used in connection with, or to facilitate, a restricted transaction, and includes—

''(i) a credit card system;

''(ii) an international, national, regional, or local network used to effect a credit transaction, an electronic fund transfer, or a money transmitting service; and

''(iii) any other system that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic fund transfers, or money transmitting services.

''(B) PERSONS DESCRIBED.—A person referred to in subparagraph (A) is—

''(i) a creditor;

''(ii) a credit card issuer;

''(iii) a financial institution;

''(iv) an operator of a terminal at which an electronic fund transfer may be initiated;

''(v) a money transmitting business; or

''(vi) a participant in an international, national, regional, or local network used to effect a credit transaction, electronic fund transfer, or money transmitting service.

''(3) RESTRICTED TRANSACTION.—The term 'restricted transaction' means a transaction or transmittal, on behalf of an individual who places an unlawful drug importation request to any person engaged in the operation of an unregistered foreign pharmacy, of—

''(A) credit, or the proceeds of credit, extended to or on behalf of the individual for the purpose of the unlawful drug importation request (including credit extended through the use of a credit card);

''(B) an electronic fund transfer or funds transmitted by or through a money transmitting business, or the proceeds of an electronic fund transfer or money transmitting service, from or on behalf of the individual for the purpose of the unlawful drug importation request;

''(C) a check, draft, or similar instrument which is drawn by or on behalf of the individual for the purpose of the unlawful drug importation request and is drawn on or payable at or through any financial institution; or

''(D) the proceeds of any other form of financial transaction (identified by the Board by regulation) that involves a financial institution as a payor or financial intermediary on behalf of or for the benefit of the individual for the purpose of the unlawful drug importation request.

''(4) UNLAWFUL DRUG IMPORTATION REQUEST.—The term 'unlawful drug importation request' means the request, or transmittal of a request, made to an unregistered foreign pharmacy for a prescription drug by mail (including a private carrier), facsimile, phone, or electronic mail, or by a means that involves the use, in whole or in part, of the Internet.

''(5) UNREGISTERED FOREIGN PHARMACY.—The term 'unregistered foreign pharmacy' means a person in a country other than the United States that is not a registered exporter under section 804.

''(6) OTHER DEFINITIONS.—

''(A) CREDIT; CREDITOR; CREDIT CARD.—The terms 'credit', 'creditor', and 'credit card' have the meanings given the terms in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

''(B) ACCESS DEVICE; ELECTRONIC FUND TRANSFER.—The terms 'access device' and 'electronic fund transfer'—

''(i) have the meaning given the term in section 903 of the Electronic Fund Transfer Act (15 U.S.C. 1693a); and

''(ii) the term 'electronic fund transfer' also includes any fund transfer covered under Article 4A of the Uniform Commercial Code, as in effect in any State.

''(C) FINANCIAL INSTITUTION.—The term 'financial institution'—

''(i) has the meaning given the term in section 903 of the Electronic Transfer Fund Act (15 U.S.C. 1693a); and

''(ii) includes a financial institution (as defined in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809)).

''(D) MONEY TRANSMITTING BUSINESS; MONEY TRANSMITTING SERVICE.—The terms 'money transmitting business' and 'money transmitting service' have the meaning given the terms in section 5330(d) of title 31, United States Code.

''(E) BOARD.—The term 'Board' means the Board of Governors of the Federal Reserve System.

''(7) POLICIES AND PROCEDURES REQUIRED TO PREVENT RESTRICTED TRANSACTIONS.—

''(A) REGULATIONS.—The Board shall promulgate regulations requiring—

''(i) an operator of a credit card system;

''(ii) an operator of an international, national, regional, or local network used to effect a credit transaction, an electronic fund transfer, or a money transmitting service;

''(iii) an operator of any other payment system that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic transfers or money transmitting services where at least one party to the transaction or transfer is an individual; and

''(iv) any other person described in paragraph (2)(B) and specified by the Board in such regulations,

to establish policies and procedures that are reasonably designed to prevent the introduction of a restricted transaction into a payment system or the completion of a restricted transaction using a payment system

''(B) REQUIREMENTS FOR POLICIES AND PROCEDURES.—In promulgating regulations under subparagraph (A), the Board shall—

''(i) identify types of policies and procedures, including nonexclusive examples, that shall be considered to be reasonably designed to prevent the introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system; and

''(ii) to the extent practicable, permit any payment system, or person described in paragraph (2)(B), as applicable, to choose among alternative means of preventing the introduction or completion of restricted transactions.

''(C) NO LIABILITY FOR BLOCKING OR REFUSING TO HONOR RESTRICTED TRANSACTION.—

''(i) IN GENERAL.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, and any participant in such payment system that prevents or otherwise refuses to honor transactions in an effort to implement the policies and procedures required under this subsection or to otherwise comply with this subsection shall not be liable to any party for such action.

''(ii) COMPLIANCE.—A person described in paragraph (2)(B) meets the requirements of this subsection if the person relies on and complies with the policies and procedures of a payment system of which the person is a member or in which the person is a participant, and such policies and procedures of the payment system comply with the requirements of the regulations promulgated under subparagraph (A).

''(D) ENFORCEMENT.—

''(i) IN GENERAL.—This section shall be enforced by the Federal functional regulators and the Federal Trade Commission under applicable law in the manner provided in section 505(a) of the Gramm-Leach-Bliley Act (15 U.S.C. 6805(a)).

''(ii) FACTORS TO BE CONSIDERED.—In considering any enforcement action under this subsection against a payment system or person described in paragraph (2)(B), the Federal functional regulators and the Federal Trade Commission shall consider the following factors:

''(I) The extent to which the payment system or person knowingly permits restricted transactions.

''(II) The history of the payment system or person in connection with permitting restricted transactions.

''(III) The extent to which the payment system or person has established and is maintaining policies and procedures in compliance with regulations prescribed under this subsection.

''(8) TRANSACTIONS PERMITTED.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, is authorized to engage in transactions with foreign pharmacies in connection with investigating violations or potential violations of any rule or requirement adopted by the payment system or person in connection with complying with paragraph (7). A payment system, or such a person, and its agents and employees shall not be found to be in violation of, or liable under, any Federal, State or other law by virtue of engaging in any such transaction.

''(9) RELATION TO STATE LAWS.—No requirement, prohibition, or liability may be imposed on a payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, under the laws of any state with respect to any payment transaction by an individual because the payment transaction involves a payment to a foreign pharmacy.

''(10) TIMING OF REQUIREMENTS.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, must adopt policies and procedures reasonably designed to comply with any regulations required under paragraph (7) within 60 days after such regulations are issued in final form.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall take effect on the day that is 90 days after the date of enactment of this title.

(c) IMPLEMENTATION.—The Board of Governors of the Federal Reserve System shall promulgate regulations as required by subsection (g)(7) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), as added by subsection (a), not later than 90 days after the date of enactment of this title.

SEC. ___9. IMPORTATION EXEMPTION UNDER CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT.

Section 1006(a)(2) of the Controlled Substances Import and Export Act (21 U.S.C. 956(a)(2)) is amended by striking ''not import the controlled substance into the United States in an amount that exceeds 50 dosage units of the controlled substance.'' and inserting ''import into the United States not more than 10 dosage units combined of all such controlled substances.''.

SA 4743. Mr. KERRY submitted an amendment intended to be proposed by him to the bill S. 3711, to enhance the energy independence and security of the United States by providing for exploration, development, and production activities for mineral resources in the Gulf of Mexico, and for other purposes; which was ordered to lie on the table; as follows:

At the end, add the following:

SEC. 6. ENERGY EMERGENCY DISASTER RELIEF LOANS TO SMALL BUSINESS AND AGRICULTURAL PRODUCERS.

(a) DEFINITIONS.—In this section:

(1) ADMINISTRATOR.—The term ''Administrator'' means the Administrator of the Small Business Administration; and

(2) SMALL BUSINESS CONCERN.—The term ''small business concern'' has the meaning given the term in section 3 of the Small Business Act (15 U.S.C. 632).

(b) SMALL BUSINESS PRODUCER ENERGY EMERGENCY DISASTER LOAN PROGRAM.—

(1) DISASTER LOAN AUTHORITY.—Section 7(b) of the Small Business Act (15 U.S.C. 636(b)) is amended by inserting immediately after paragraph (3) the following:

''(4) ENERGY DISASTER LOANS.—

''(A) DEFINITIONS.—In this paragraph—

''(i) the term 'base price index' means the moving average of the closing unit price on the New York Mercantile Exchange for heating oil, natural gas, gasoline, or propane for the 10 days that correspond to the trading days described in clause (ii) in each of the most recent 2 preceding years;

''(ii) the term 'current price index' means the moving average of the closing unit price on the New York Mercantile Exchange, for the 10 most recent trading days, for contracts to purchase heating oil, natural gas, gasoline, or propane during the subsequent calendar month, commonly known as the 'front month'; and

''(iii) the term 'significant increase' means—

''(I) with respect to the price of heating oil, natural gas, gasoline, or propane, any time the current price index exceeds the base price index by not less than 40 percent; and

''(II) with respect to the price of kerosene, any increase which the Administrator, in consultation with the Secretary of Energy, determines to be significant.

''(B) LOAN AUTHORITY.—The Administrator may make such loans, either directly or in cooperation with banks or other lending institutions through agreements to participate on an immediate or deferred basis, to assist a small business concern that has suffered or that is likely to suffer substantial economic injury on or after January 1, 2005, as the result of a significant increase in the price of heating oil, natural gas, gasoline, propane, or kerosene occurring on or after January 1, 2005.

''(C) INTEREST RATE.—Any loan or guarantee extended pursuant to this paragraph shall be made at the same interest rate as economic injury loans under paragraph (2).

''(D) MAXIMUM AMOUNT.—No loan may be made under this paragraph, either directly or in cooperation with banks or other lending institutions through agreements to participate on an immediate or deferred basis, if the total amount outstanding and committed to the borrower under this subsection would exceed $1,500,000, unless such borrower constitutes a major source of employment in its surrounding area, as determined by the Administrator, in which case the Administrator, in the discretion of the Administrator, may waive the $1,500,000 limitation.

''(E) DISASTER DECLARATION.—For purposes of assistance under this paragraph—

''(i) a declaration of a disaster area based on conditions specified in this paragraph shall be required, and shall be made by the President or the Administrator; or

''(ii) if no declaration has been made pursuant to clause (i), the Governor of a State in which a significant increase in the price of heating oil, natural gas, gasoline, propane, or kerosene has occurred may certify to the Administrator that small business concerns have suffered economic injury as a result of such increase and are in need of financial assistance which is not otherwise available on reasonable terms in that State, and upon receipt of such certification, the Administrator may make such loans as would have been available under this paragraph if a disaster declaration had been issued.

''(F) CONVERSION.—Notwithstanding any other provision of law, loans made under this paragraph may be used by a small business concern described in subparagraph (B) to convert from the use of heating oil, natural gas, gasoline, propane, or kerosene to a renewable or alternative energy source, including agriculture and urban waste, geothermal energy, cogeneration, solar energy, wind energy, or fuel cells.''.

(2) CONFORMING AMENDMENTS.—Section 3(k) of the Small Business Act (15 U.S.C. 632(k)) is amended—

(A) by inserting '', a significant increase in the price of heating oil, natural gas, gasoline, propane, or kerosene,'' after ''civil disorders''; and

(B) by inserting ''other'' before ''economic''.

(c) AGRICULTURAL PRODUCER EMERGENCY LOANS.—

(1) IN GENERAL.—Section 321(a) of the Consolidated Farm and Rural Development Act (7 U.S.C. 1961(a)) is amended—

(A) in the first sentence—

(i) by striking ''aquaculture operations have'' and inserting ''aquaculture operations (i) have''; and

(ii) by inserting before '': *Provided*,'' the following: '', or (ii)(I) are owned or operated by such an applicant that is also a small business concern (as defined in section 3 of the Small Business Act (15 U.S.C. 632)), and (II) have suffered or are likely to suffer substantial economic injury on or after January 1, 2005, as the result of a significant increase in energy costs or input costs from energy sources occurring on or after January 1, 2005, in connection with an energy emergency declared by the President or the Secretary'';

(B) in the third sentence, by inserting before the period at the end the following: ''or by an energy emergency declared by the President or the Secretary''; and

(C) in the fourth sentence—

(i) by striking ''or natural disaster'' each place that term appears and inserting '', natural disaster, or energy emergency''; and

(ii) by inserting ''or declaration'' after ''emergency designation''.

(2) FUNDING.—Funds available on the date of enactment of this Act for emergency loans under subtitle C of the Consolidated Farm and Rural Development Act (7 U.S.C. 1961 et seq.) shall be available to carry out the amendments made by paragraph (1) to meet the needs resulting from natural disasters.

(d) GUIDELINES AND RULEMAKING.—

(1) GUIDELINES.—Not later than 30 days after the date of enactment of this Act, the Administrator and the Secretary of Agriculture shall each issue guidelines to carry out subsections (b) and (c), respectively, and the amendments made thereby, which guidelines shall become effective on the date of their issuance.

(2) RULEMAKING.—Not later than 30 days after the date of enactment of this Act, the Administrator, after consultation with the Secretary of Energy, shall promulgate regulations specifying the method for determining a significant increase in the price of kerosene under section 7(b)(4)(A)(iii)(II) of the Small Business Act, as added by this section.

(e) REPORTS.—

(1) SMALL BUSINESS ADMINISTRATION.—Not later than 12 months after the date on which the Administrator issues guidelines under subsection (d)(1), and annually thereafter, until the date that is 12 months after the end of the effective period of section 7(b)(4) of the Small Business Act, as added by this section, the Administrator shall submit to the Committee on Small Business and Entrepreneurship of the Senate and the Committee on Small Business of the House of Representatives, a report on the effectiveness of the assistance made available under section 7(b)(4) of the Small Business Act, as added by this section, including—

(A) the number of small business concerns that applied for a loan under such section 7(b)(4) and the number of those that received such loans;

(B) the dollar value of those loans;

(C) the States in which the small business concerns that received such loans are located;

(D) the type of energy that caused the significant increase in the cost for the participating small business concerns; and

(E) recommendations for ways to improve the assistance provided under such section 7(b)(4), if any.

(2) DEPARTMENT OF AGRICULTURE.—Not later than 12 months after the date on which the Secretary of Agriculture issues guidelines under subsection (d)(1), and annually thereafter, until the date that is 12 months after the end of the effective period of the amendments made to section 321(a) of the Consolidated Farm and Rural Development Act (7 U.S.C. 1961(a)) by this section, the Secretary shall submit to the Committee on Small Business and Entrepreneurship and the Committee on Agriculture, Nutrition, and Forestry of the Senate and to the Committee on Small Business and the Committee on Agriculture of the House of Representatives, a report that—

(A) describes the effectiveness of the assistance made available under section 321(a) of the Consolidated Farm and Rural Development Act (7 U.S.C. 1961(a)), as amended by this section; and

(B) contains recommendations for ways to improve the assistance provided under such section 321(a).

(f) EFFECTIVE DATE.—

(1) SMALL BUSINESS.—The amendments made by subsection (b) shall apply during the 4-year period beginning on the earlier of the date on which guidelines are published by the Administrator under subsection (d)(1) or 30 days after the date of enactment of this Act, with respect to assistance under section 7(b)(4) of the Small Business Act, as added by this section.

(2) AGRICULTURE.—The amendments made by subsection (c) shall apply during the 4-year period beginning on the earlier of the date on which guidelines are published by the Secretary of Agriculture under subsection (d)(1) or 30 days after the date of enactment of this Act, with respect to assistance under section 321(a) of the Consolidated Farm and Rural Development Act (7 U.S.C. 1961(a)), as amended by this section.

SA 4744. Mr KERRY (for himself and Mr. JEFFORDS) submitted an amendment intended to be proposed by him to the bill S. 3711, to enhance the energy independence and security of the United States by providing for exploration, development, and production activities for mineral resources in the Gulf of Mexico, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. FEDERAL RENEWABLE PORTFOLIO STANDARD.

Title VI of the Public Utility Regulatory Policies Act of 1978 (16 U.S.C. 2601 et seq.) is amended by adding at the end the following:

''SEC. 610. FEDERAL RENEWABLE PORTFOLIO STANDARD.

''(a) DEFINITIONS.—In this section:

''(1) BIOMASS.—

''(A) IN GENERAL.—The term 'biomass' means—

''(i) organic material from a plant that is planted for the purpose of producing energy;

''(ii) nonhazardous, cellulosic, or agricultural waste material that—

''(I) is segregated from other waste materials; and

''(II) is derived from—

''(aa) a forest-related resource, including—

''(AA) mill and harvesting residue;

''(BB) precommercial thinnings;

''(CC) slash; and

''(DD) brush;

''(bb) agricultural resources, including—

''(AA) orchard tree crops;

''(BB) vineyards;

''(CC) grains;

''(DD) legumes;

''(EE) sugar; and

''(FF) other crop by-products or residues; or

''(cc) miscellaneous waste, such as—

''(AA) waste pallet;

''(BB) crate; and

''(CC) landscape or right-of-way tree trimmings; and

''(iii) animal waste—

''(I) that is converted to a fuel rather than directly combusted; and

''(II) the residue of which is converted to—

''(aa) a biological fertilizer;

''(bb) oil; or

''(cc) activated carbon.

''(B) EXCLUSIONS.—The term 'biomass' does not include—

''(i) municipal solid waste that is incinerated;

''(ii) recyclable post-consumer waste paper;

''(iii) painted, treated, or pressurized wood;

''(iv) wood contaminated with plastics or metals; or

''(v) tires.

''(2) DISTRIBUTED GENERATION.—The term 'distributed generation' means reduced electricity consumption on the electric grid due to use by a customer of renewable energy generated at a customer site.

''(3) INCREMENTAL HYDROPOWER.—The term 'incremental hydropower' means additional generation achieved after January 1, 2005, as a result of increased efficiency at a hydroelectric dam that was placed in service before that date.

''(4) LANDFILL GAS.—The term 'landfill gas' means gas generated from the decomposition of household solid waste, commercial solid waste, or industrial solid waste disposed of in a municipal solid waste landfill unit (as those terms are defined in regulations promulgated pursuant to subtitle D of the Solid Waste Disposal Act (42 U.S.C. 6941 et seq.)).

''(5) RENEWABLE ENERGY.—The term 'renewable energy' means electricity generated from—

''(A) a renewable energy source; or

''(B) hydrogen that is produced from a renewable energy source.

''(6) RENEWABLE ENERGY SOURCE.—The term 'renewable energy source' means—

''(A) wind;

''(B) ocean waves;

''(C) biomass;

''(D) solar energy;

''(E) landfill gas;

''(F) incremental hydropower; or

''(G) geothermal.

''(7) RETAIL ELECTRIC SUPPLIER.—The term 'retail electric supplier' means a person or entity that, with respect to an applicable calendar year under subsection (b)(1)—

''(A) sells retail electricity to consumers; and

''(B) sold not less than 500,000 megawatt-hours of electric energy to consumers for purposes other than resale during the preceding calendar year.

''(b) RENEWABLE ENERGY REQUIREMENTS.—

''(1) SUBMISSION OF CREDITS.—

''(A) IN GENERAL.—Not later than April 30, 2007, and annually thereafter, each retail electric supplier shall submit to the Secretary renewable energy credits in a quantity equal to the product obtained by multiplying—

''(i) the total kilowatt-hours of nonhydropower (excluding incremental hydropower) electricity sold by the retail electric supplier to retail consumers during the preceding calendar year; and

''(ii) the applicable percentage under the table contained in subsection (c).

''(B) FORM OF CREDITS.—A credit submitted under subparagraph (A) shall be—

''(i) a renewable energy credit issued to the retail electric supplier under subsection (d)(2);

''(ii) a renewable energy credit obtained by purchase or exchange under subsection (d)(3);

''(iii) a renewable energy credit purchased from the United States under subsection (d)(4); or

''(iv) any combination of credits described in clauses (i) through (iii).

''(C) PROHIBITION ON DOUBLE COUNTING.—A credit may be counted for purposes of compliance with this subsection only once.

''(2) CARRYOVER.—A renewable energy credit received by a retail electric supplier during a calendar year that is not used to satisfy the requirement for that year under paragraph (1) may be carried over for use during 1 of the following 2 calendar years.

''(c) REQUIRED ANNUAL PERCENTAGE.—Of the total quantity of nonhydropower (excluding incremental hydropower) electricity sold by a retail electric supplier during a calendar year, the quantity generated by renewable energy sources shall be not less than the percentage described in the following table:

''Calendar year	Required percentage
2007–2009	5
2010–2014	10
2015–2019	15
2020 and thereafter	20

''(d) RENEWABLE ENERGY CREDIT PROGRAM.—

''(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this section, the Secretary shall establish a program under which the Secretary shall issue, monitor the sale and exchange of, sell, and track renewable energy credits.

''(2) ISSUANCE OF CREDITS.—

''(A) ISSUANCE.—

''(i) IN GENERAL.—Except as provided in clauses (ii) and (iii), the Secretary shall issue to an entity that submits an application under subparagraph (B) 1 renewable energy credit for each kilowatt-hour of renewable energy generated by the entity in any State during the preceding calendar year for—

''(I) sale for retail consumption; or

''(II) use by the generator.

''(ii) DISTRIBUTED GENERATION.—Notwithstanding clause (i), the Secretary shall issue to an entity that submits an application under subparagraph (B) 3 renewable energy credits for each kilowatt-hour of distributed generation as a result of actions of the entity.

''(iii) COMBINATION OF SOURCES.—If a kilowatt-hour of renewable energy is generated through the use of a renewable energy resource and a nonrenewable energy resource, the Secretary shall issue an applicable renewable energy credit based on the ratio that—

''(I) the quantity of renewable energy resource used to generate the kilowatt-hour of renewable energy; bears to

''(II) the total quantity of resources used to generate the kilowatt-hour of renewable energy.

''(B) APPLICATION.—

''(i) IN GENERAL.—An entity that generates renewable energy may submit to the Secretary an application for the issuance of renewable energy credits.

''(ii) INCLUSIONS.—An application under clause (i) shall include a description of—

''(I) the type of renewable energy resource used by the entity to produce the renewable energy;

''(II) the State in which the renewable energy was produced; and

''(III) any other information the Secretary determines to be appropriate.

''(C) VESTING.—A renewable energy credit shall vest with the owner of the system or facility that generates the renewable energy, unless the owner explicitly transfers the credit.

''(D) IDENTIFICATION.—For purposes of issuing, selling, and tracking renewable energy credits, the Secretary shall identify the credits based on the type and date of generation of the renewable energy for which the credit is provided.

''(E) CONTRACT SALES.—For purposes of this section, a retail electric supplier that purchases renewable energy from a generator pursuant to a contract under section 210 shall be considered to be the generator of the renewable energy.

''(F) VOLUNTARY PARTICIPATION.—The Secretary may issue a renewable energy credit under this paragraph to an entity that is not subject to the requirements of this Act only if the entity—

''(i) meets the terms and conditions of this Act to the same extent as an entity subject to the requirements of this Act; and

''(ii) submits an application under subparagraph (B).

''(3) SALE AND EXCHANGE OF CREDITS.—

''(A) IN GENERAL.—A renewable energy credit may be sold or exchanged by—

''(i) the entity that is issued the renewable energy credit under paragraph (2); or

''(ii) any other entity that acquires the renewable energy credit.

''(B) REQUIREMENT.—A sale or exchange of a credit under subparagraph (A) shall be carried out in accordance with applicable contracts and laws, including laws relating to the spot market.

''(4) PURCHASE FROM UNITED STATES.—

''(A) IN GENERAL.—The Secretary shall offer for sale renewable energy credits at a price equal to the lesser of, as adjusted for inflation under subparagraph (B)—

''(i) 3 cents per kilowatt-hour covered by the credit; and

''(ii) an amount equal to 110 percent of the average market value of the credits for the applicable compliance period.

''(B) ADJUSTMENT FOR INFLATION.—On January 1, 2007, and annually thereafter, the Secretary shall adjust for inflation the price to be charged for a renewable energy credit for the appropriate calendar year.

''(e) ENFORCEMENT.—

''(1) IN GENERAL.—A retail electric supplier that does not submit renewable energy credits in accordance with subsection (b) shall be subject to a civil penalty in an amount equal to the product obtained by multiplying—

''(A) the difference between—

''(i) the number of renewable energy credits submitted by the retail electric supplier; and

''(ii) the number of credits required to be submitted by the retail electric supplier under subsection (b); and

''(B) the lesser of—

''(i) 4.5 cents; and

''(ii) an amount equal to 300 percent of the average market value of credits for the applicable compliance period.

''(2) COLLECTION OF INFORMATION.—The Secretary may collect such information as the Secretary determines to be necessary to verify and audit—

''(A) the annual electric energy generation and renewable energy generation of any entity that applies for renewable energy credits under this section;

''(B) the validity of renewable energy credits submitted by a retail electric supplier to the Secretary; and

''(C) the total amount of electricity sales of all retail electric suppliers.

''(f) CONSUMER ALLOCATION.—

''(1) IN GENERAL.—A retail electric supplier shall charge each class of consumers of the retail electric supplier a rate that proportionally reflects the percentage of the cost to the retail electric supplier of generating or acquiring the annual percentage of renewable energy required under subsection (b).

''(2) PROHIBITION OF MISREPRESENTATION.—A retail electric supplier shall not make any representation to a customer or prospective customer of the retail electric supplier regarding product content or description if the content or description has been or will be modified by the retail electric supplier solely for purposes of complying with this section.

''(g) STATE RENEWABLE ENERGY GRANT PROGRAM.—

''(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this section, the Secretary shall establish a program under which the Secretary shall distribute amounts received from sales under subsection (d)(4), and from penalties under subsection (e)(1), to State energy agencies for use in accordance with this section.

''(2) USE OF FUNDS.—A State energy agency shall use amounts received under this subsection to carry out a grant program to provide for—

''(A) renewable energy research and development;

''(B) loan guarantees to encourage construction of renewable energy facilities;

''(C) consumer rebate or other programs to offset the costs of small residential or small commercial renewable energy systems, including solar hot water; or

''(D) promotion of distributed generation.

''(3) PRIORITY.—In allocating amounts under this subsection, the Secretary shall give priority to, as determined by the Secretary—

''(A) States in regions with a disproportionately small share of economically-sustainable renewable energy generation capacity; and

''(B) States the grant programs of which are most likely to stimulate or enhance innovative renewable energy technologies.

''(h) EFFECT ON OTHER STATE PROGRAMS.—Nothing in this section precludes any State from requiring additional renewable energy generation capacity in the State pursuant to a renewable energy program conducted by the State.''.

SA 4745. Mr. KERRY submitted an amendment intended to be proposed by him to the bill S. 3711, to enhance the energy independence and security of the United States by providing for exploration, development, and production activities for mineral resources in the Gulf of Mexico, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. FUNDING FOR ALTERNATIVE INFRASTRUCTURE FOR THE DISTRIBUTION OF TRANSPORTATION FUELS.

(a) IN GENERAL.—There is established in the Treasury of the United States a trust fund, to be known as the ''Alternative Fueling Infrastructure Trust Fund'' (referred to in this section as the ''Trust Fund''), consisting of such amounts as are deposited into the Trust Fund under subsection (b) and any interest earned on investment of amounts in the Trust Fund.

(b) PENALTIES.—The Secretary of Transportation shall remit 90 percent of the amount collected in civil penalties under section 32912 of title 49, United States Code, to the Trust Fund.

(c) GRANT PROGRAM.—

(1) IN GENERAL.—The Secretary of Energy shall obligate such sums as are available in the Trust Fund to establish a grant program to increase the number of locations at which consumers may purchase alternative transportation fuels.

(2) ADMINISTRATION.—

(A) IN GENERAL.—The Secretary of Energy may award grants under this subsection to—

(i) individual fueling stations; and

(ii) corporations (including nonprofit corporations) with demonstrated experience in the administration of grant funding for the purpose of alternative fueling infrastructure.

(B) MAXIMUM AMOUNT OF GRANTS.—A grant provided under this subsection may not exceed—

(i) $150,000 for each site of an individual fueling station; and

(ii) $500,000 for each corporation (including a nonprofit corporation).

(C) PRIORITIZATION.—The Secretary of Energy shall prioritize the provision of grants under this subsection to recognized nonprofit corporations that have proven experience and demonstrated technical expertise in the establishment of alternative fueling infrastructure, as determined by the Secretary of Energy.

(D) ADMINISTRATIVE EXPENSES.—Not more than 10 percent of the funds provided in any grant may be used by the recipient of the grant to pay administrative expenses.

(E) NUMBER OF VEHICLES.—In providing grants under this subsection, the Secretary of Energy shall consider the number of vehicles in service capable of using a specific type of alternative fuel.

(F) MATCH.—Grant recipients shall provide a non-Federal match of not less than $1 for every $3 of grant funds received under this subsection.

(G) LOCATIONS.—Each grant recipient shall select the locations for each alternative fuel station to be constructed with grant funds received under this subsection on a formal, open, and competitive basis.

(H) USE OF INFORMATION IN SELECTION OF RECIPIENTS.—In selecting grant recipients under this subsection, the Secretary of Energy may consider—

(i) public demand for each alternative fuel in a particular county based on State registration records indicating the number of vehicles that may be operated using alternative fuel; and

(ii) the opportunity to create or expand corridors of alternative fuel stations along interstates or highways.

(3) USE OF GRANT FUNDS.—Grant funds received under this subsection may be used to—

(A) construct new facilities to dispense alternative fuels;

(B) purchase equipment to upgrade, expand, or otherwise improve existing alternative fuel facilities; or

(C) purchase equipment or pay for specific turnkey fueling services by alternative fuel providers.

(4) FACILITIES.—Facilities constructed or upgraded with grant funds under this subsection shall—

(A) provide alternative fuel available to the public for a period not less than 4 years;

(B) establish a marketing plan to advance the sale and use of alternative fuels;

(C) prominently display the price of alternative fuel on the marquee and in the station;

(D) provide point of sale materials on alternative fuel;

(E) clearly label the dispenser with consistent materials;

(F) price the alternative fuel at the same margin that is received for unleaded gasoline; and

(G) support and use all available tax incentives to reduce the cost of the alternative fuel to the lowest practicable retail price.

(5) OPENING OF STATIONS.—

(A) IN GENERAL.—Not later than the date on which each alternative fuel station begins to offer alternative fuel to the public, the grant recipient that used grant funds to construct the station shall notify the Secretary of Energy of the opening.

(B) WEBSITE.—The Secretary of Energy shall add each new alternative fuel station to the alternative fuel station locator on the website of the Department of Energy when the Secretary of Energy receives notification under this subsection.

(6) REPORTS.—Not later than 180 days after the receipt of a grant award under this subsection, and every 180 days thereafter, each grant recipient shall submit a report to the Secretary of Energy that describes—

(A) the status of each alternative fuel station constructed with grant funds received under this subsection;

(B) the quantity of alternative fuel dispensed at each station during the preceding 180-day period; and

(C) the average price per gallon of the alternative fuel sold at each station during the preceding 180-day period.

SA 4746. Mr. SMITH (for himself, Mr. MENENDEZ, Ms. SNOWE, Mr. KERRY, Mr. SALAZAR, Ms. CANTWELL, Mr. LIEBERMAN, Mr. KENNEDY, Mr. ALLARD, Mr. WYDEN, Mrs. CLINTON, and Mr. DODD) submitted an amendment intended to be proposed by him to the bill S. 3711, to enhance the energy independence and security of the United States by providing for exploration, development, and production activities for mineral resources in the Gulf of Mexico, and for other purposes; which was ordered to lie on the table; as follows:

At the end, add the following:

SEC. 6. INVESTMENT TAX CREDITS.

(a) EXTENSION AND MODIFICATION OF INVESTMENT TAX CREDIT WITH RESPECT TO SOLAR ENERGY PROPERTY AND QUALIFIED FUEL CELL PROPERTY.—

(1) SOLAR ENERGY PROPERTY.—Paragraphs (2)(A)(i)(II) and (3)(A)(ii) of section 48(a) of the Internal Revenue Code of 1986 are each amended by striking ''2008'' and inserting ''2016''.

(2) ELIGIBLE FUEL CELL PROPERTY.—Paragraph (1)(E) of section 48(c) of the Internal Revenue Code of 1986 is amended by striking ''2007'' and inserting ''2015''.

(3) CREDITS ALLOWED AGAINST THE ALTERNATIVE MINIMUM TAX.—Section 38(c)(4)(B) of the Internal Revenue Code of 1986 (defining specified credits) is amended by striking the period at the end of clause (ii)(II) and inserting '', and'', and by adding at the end the following new clause:

''(iii) the portion of the investment credit under section 46(2) as determined under section 48(a)(2)(A)(i).''.

(b) EXTENSION AND MODIFICATION OF CREDIT FOR RESIDENTIAL ENERGY EFFICIENT PROPERTY.—

(1) EXTENSION.—Section 25D of the Internal Revenue Code of 1986 (relating to termination) is amended by striking ''2007'' and inserting ''2015''.

(2) MODIFICATION OF MAXIMUM CREDIT.—Paragraph (1) of section 25D(b) of the Internal Revenue Code of 1986 (relating to limitations) is amended to read as follows:

''(1) MAXIMUM CREDIT.—The credit allowed under subsection (a) for any taxable year shall not exceed—

''(A) $1,000 with respect to each half kilowatt of capacity of qualified photovoltaic property for which qualified photovoltaic property expenditures are made,

''(B) $2,000 with respect to any qualified solar water heating property expenditures, and

''(C) $500 with respect to each half kilowatt of capacity of qualified fuel cell property (as

defined in section 48(c)(1)) for which qualified fuel cell property expenditures are made.''.

(3) CREDIT ALLOWED AGAINST ALTERNATIVE MINIMUM TAX.—

(A) IN GENERAL.—Section 25D(b) of the Internal Revenue Code of 1986 (as amended by subsection (b)) is amended by adding at the end the following new paragraph:

''(3) CREDIT ALLOWED AGAINST ALTERNATIVE MINIMUM TAX.—The credit allowed under subsection (a) for the taxable year shall not exceed the excess of—

''(A) the sum of the regular tax liability (as defined in section 26(b)) plus the tax imposed by section 55, over

''(B) the sum of the credits allowable under subpart A of part IV of subchapter A and section 27 for the taxable year.''.

(B) CONFORMING AMENDMENT.—Subsection (c) of section 25D of such Code is amended to read as follows:

''(c) CARRYFORWARD OF UNUSED CREDIT.—If the credit allowable under subsection (a) for any taxable year exceeds the limitation imposed by subsection (b)(3) for such taxable year, such excess shall be carried to the succeeding taxable year and added to the credit allowable under subsection (a) for such succeeding taxable year.''.

(4) EFFECTIVE DATE.—The amendments made by this subsection shall apply to taxable years beginning after December 31, 2006.

SA 4747. Mr. WARNER submitted an amendment intended to be proposed by him to the bill S. 3711, to enhance the energy independence and security of the United States by providing for exploration, development, and production activities for mineral resources in the Gulf of Mexico, and for other purposes; which was ordered to lie on the table; as follows:

Beginning on page 17, strike line 19 and all that follows through page 18, line 17 and insert the following:

(f) LIMITATIONS ON AMOUNT OF DISTRIBUTED QUALIFIED OUTER CONTINENTAL SHELF REVENUES AND COVERED REVENUES.—

(1) IN GENERAL.—Subject to paragraph (2), the total amount of qualified outer Continental Shelf revenues and covered revenues made available under subsection (a)(2) and section 6(j)(1)(B) shall not exceed $500,000,000 for each of fiscal years 2016 through 2055.

(2) EXPENDITURES.—For the purpose of paragraph (1), for each of fiscal years 2016 through 2055, expenditures under subsection (a)(2) and section 6(j)(1)(B) shall be net of receipts from that fiscal year from any area in the 181 Area in the Eastern Planning Area, the 181 South Area, or any area off the coastline of a covered State.

(3) PRO RATA REDUCTIONS.—If paragraph (1) limits the amount of qualified outer Continental Shelf revenue or covered revenues that would be paid under subparagraphs (A) and (B) of subsection (a)(2) or clauses (i) and (ii) of section 6(j)(1)(B)—

(A) the Secretary shall reduce the amount of qualified outer Continental Shelf revenue and covered revenue provided to each recipient on a pro rata basis; and

(B) any remainder of the qualified outer Continental Shelf revenues and covered revenues shall revert to the general fund of the Treasury.

SEC. 6. OFFSHORE OIL AND GAS LEASING IN AREAS OUTSIDE THE GULF OF MEXICO.

(a) DEFINITIONS.—In this section:

(1) ADJACENT ZONE.—The term ''Adjacent Zone'' means the Adjacent Zone of each State, as defined by the lines extending seaward and defining the adjacent Zone of each State indicated on the maps for each outer Continental Shelf region entitled—

(A) ''Alaska OCS Region State Adjacent Zone and OCS Planning Areas'';

(B) ''Pacific OCS Region State Adjacent Zones and OCS Planning Areas''; and

(C) ''Atlantic OCS Region State Adjacent Zones and OCS Planning Areas'';

all of which are dated September 2005 and on file in the Office of the Director, Minerals Management Service.

(2) COVERED REVENUES.—

(A) IN GENERAL.—The term ''covered revenues'' means all rentals, royalties, bonus bids, and other sums due and payable to the United States from leases entered into on or after the date of enactment of this Act in a moratorium area.

(B) EXCLUSIONS.—The term ''covered revenues'' does not include—

(i) revenues from the forfeiture of a bond or other surety securing obligations other than royalties, civil penalties, or royalties taken by the Secretary in-kind and not sold; or

(ii) revenues generated from leases subject to section 8(g) of the Outer Continental Shelf Lands Act (43 U.S.C. 1337(g)).

(3) COVERED STATE.—The term ''covered State'' means—

(A) a State for which—

(i) the Governor of the State requests the Secretary to allow natural gas or oil or natural gas leasing in a moratorium area; and

(ii) the Secretary allows the leasing; and

(B) effective for fiscal year 2017 and each fiscal year thereafter, a State—

(i) off which oil and gas activities on the outer Continental Shelf are conducted under a lease entered into on or after the date of enactment of this Act;

(ii) that is offshore of any State that is not a Gulf producing State; and

(iii) that does not have an area described in section 2(6)(B)(i) off the coast of the State, as determined on the basis of the administrative lines established by the Secretary under the notice published on January 3, 2006 (71 Fed. Reg. 127).

(4) LEASE.—The term ''lease'' includes a natural gas lease under section 8(q) of the Outer Continental Shelf Lands Act (43 U.S.C. 1337(q)).

(5) MORATORIUM AREA.—The term ''moratorium area'' means—

(A) any area withdrawn from disposition by leasing in the Atlantic OCS Region or the Pacific OCS Region Planning Area under the ''Memorandum on Withdrawal of Certain Areas of the United States Outer Continental Shelf from Leasing Disposition'', from 34 Weekly Comp. Pres. Doc. 1111, dated June 12, 1998; and

(B) any area of the outer Continental Shelf (other than an area in the Gulf of Mexico) as to which Congress has denied the use of appropriated funds or other means for preleasing, leasing, or related activities.

(b) PROHIBITION AGAINST LEASING.—Except as otherwise provided in this section, prior to June 30, 2012, the Secretary shall not offer a lease for oil and gas, or natural gas, in a moratorium area.

(c) OPTION TO PETITION FOR EXTENSION OF WITHDRAWAL FROM LEASING.—

(1) OPTION TO PETITION.—

(A) IN GENERAL.—The Governor of a State may submit to the Secretary a petition requesting that the Secretary extend for a period of time described in subparagraph (B) the withdrawal from leasing in a moratorium area for all or part of any area within the Adjacent Zone of the State within 125 miles of the coastline of the State.

(B) LENGTH OF EXTENSION.—

(i) IN GENERAL.—The period of time requested in a petition submitted under subparagraph (A) shall not exceed 5 years for each petition.

(ii) LIMITATION.—The Secretary shall not grant a petition submitted under subparagraph (A) that extends the remaining period of a withdrawal of an area from leasing for a total of more than 10 years.

(C) MULTIPLE PETITIONS.—A State may petition multiple times for a particular area, but not more than once per calendar year for any particular area.

(D) CONTENTS OF PETITION.—A petition submitted under subparagraph (A) may—

(i) apply to either oil and gas leasing or natural gas leasing, or both; and

(ii) request some areas to be withdrawn from all leasing and some areas only withdrawn from 1 type of leasing.

(2) ACTION BY SECRETARY.—Not later than 90 days after receipt of a petition submitted according to the guidelines described in paragraph (1), the Secretary shall approve the petition.

(3) FAILURE TO ACT.—If the Secretary fails to approve a petition in accordance with paragraph (2), the petition shall be considered to be approved 90 days after the date on which the Secretary received the petition.

(d) RESOURCE ESTIMATES.—

(1) REQUESTS.—At any time, the Governor of an affected State (acting on behalf of the State) may request the Secretary to provide a current estimate of proven and potential gas, or oil and gas, resources that may result, and resulting State revenues, in any moratorium area (or any part of the moratorium area the Governor identifies) adjacent to, or lying seaward of the coastline of, that State.

(2) RESPONSE OF SECRETARY.—Not later than 45 days after the date on which the Governor of a State requests an estimate under paragraph (1), the Secretary shall provide—

(A) a current estimate of proven and potential gas, or oil and gas, resources in any moratorium areas off the shore of a State;

(B) an estimate of potential revenues that could be shared under this Act if resources were developed and produced; and

(C) an explanation of the planning processes that could lead to the leasing, exploration, development, and production of the gas, or oil and gas, resources within the area identified.

(e) AVAILABILITY OF CERTAIN AREAS FOR LEASING.—

(1) PETITION.—

(A) IN GENERAL.—On consideration of the information received from the Secretary, the Governor (acting on behalf of the State of the Governor) may submit to the Secretary a petition requesting that the Secretary make available for leasing any portion of a moratorium area in the Adjacent Zone of the State.

(B) CONTENTS.—In a petition under subparagraph (A), a Governor may request that an area described in subparagraph (A) be made available for leasing under subsection (b) or (q), or both, of section 8 of the Outer Continental Shelf Lands Act (43 U.S.C. 1337).

(2) ACTION BY SECRETARY.—Not later than 90 days after the date of receipt of a petition under paragraph (1), the Secretary shall approve the petition unless the Secretary determines that leasing in the affected area presents a significant likelihood of incidents associated with the development of resources that would cause serious harm or damage to the marine resources of the area or of an adjacent State.

(3) FAILURE TO ACT.—If the Secretary fails to approve or deny a petition in accordance with paragraph (2), the petition shall be considered to be approved as of the date that is 90 days after the date of receipt of the petition.

(4) TREATMENT.—Notwithstanding any other provision of law, not later than 180

days after the date on which a petition is approved, or considered to be approved, under paragraph (2) or (3), the Secretary shall—

(A) treat the petition of the Governor under paragraph (1) as a proposed revision to a leasing program under section 18 of the Outer Continental Shelf Lands Act (43 U.S.C. 1344); and

(B) except as provided in paragraph (5), expedite the revision of the 5-year outer Continental Shelf oil and gas leasing program in effect as of that date to include any lease sale for any area covered by the petition.

(5) INCLUSION IN SUBSEQUENT PLANS.—

(A) IN GENERAL.—If there are less than 18 months remaining in the 5-year outer Continental Shelf oil and gas leasing program described in paragraph (4)(B), the Secretary, without consultation with any State, shall include the areas covered by the petition in lease sales under the subsequent 5-year outer Continental Shelf oil and gas leasing program.

(B) ENVIRONMENTAL ASSESSMENT.—Before modifying a 5-Year outer Continental Shelf oil and gas leasing program under subparagraph (A), the Secretary shall complete an environmental assessment that describes any anticipated environmental effect of leasing in the area covered by the petition.

(6) SPENDING LIMITATIONS.—Any Federal spending limitation with respect to preleasing, leasing, or a related activity in an area made available for leasing under this subsection shall terminate as of the date on which the petition of the Governor relating to the area is approved, or considered to be approved, under paragraph (2) or (3).

(7) APPLICATION.—This subsection shall not apply to—

(A) any area designated as a national marine sanctuary or a national wildlife refuge;

(B) any area not included in the outer Continental Shelf; or

(C) the Great Lakes (as defined in section 118(a)(3) of the Federal Water Pollution Control Act (33 U.S.C. 1268(a)(3)).

(8) GREAT LAKES.—The Great Lakes (as defined in section 118(a)(3) of the Federal Water Pollution Control Act (33 U.S.C. 1268(a)(3)))—

(A) shall not be considered part of the outer Continental Shelf under the Outer Continental Shelf Lands Act (43 U.S.C. 1331 et seq.); and

(B) shall not be subject to production.

(f) NEIGHBORING STATE CONCURRENCE.—

(1) NOTICE.—The Secretary shall provide notice to a neighboring State of any proposed lease of oil or natural gas in a moratorium area if the lease would be located within 20 miles of the nearest point on the coastline of the State.

(2) OBJECTION.—Not later than 30 days after receiving the notice, the Governor of the State may object to the issuance of the lease on grounds that the lease presents a significant risk to environmental and economic resources of the State.

(3) SECRETARY REVIEW.—If the Secretary, after review of the objection and consultation with the adjacent State, concurs that the lease presents a significant risk described in paragraph (2), and that the risk cannot be reasonably mitigated, the Secretary shall not approve an exploration plan for the lease.

(4) NONAPPLICABILITY.—This subsection does not apply to a State covered by subsection (h).

(g) NATURAL GAS LEASES.—

(1) IN GENERAL.—Beginning with the 5-year outer Continental Shelf oil and gas leasing program for 2007 through 2012, the Secretary may issue a lease under this section that authorizes development and production of gas and associated condensate and other hydrocarbon liquids in a moratorium area in accordance with regulations issued under paragraph (2).

(2) REGULATIONS.—Not later than October 1, 2006, the Secretary shall issue regulations that, for purposes of this subsection—

(A) define the term ''natural gas'' in a manner that includes—

(i) hydrocarbons and other substances in a gaseous state at atmospheric pressure and a temperature of 60 degrees Fahrenheit;

(ii) liquids that condense (gas liquids) from natural gas in the process of treatment, dehydration, decompression, or compression prior to the point for measuring volume and quality of the production established by the Secretary, acting through the Minerals Management Service;

(iii) other associated hydrocarbon liquids if the predominant component is natural gas and gas liquids; and

(iv) natural gas liquefied for transportation;

(B) provide that natural gas leases shall contain the same rights and obligations as oil and gas leases;

(C) provide that, in reviewing the adequacy of bids for natural gas leases, the Secretary, acting through the Minerals Management Service, shall exclude the value of any crude oil estimated to be discovered within the boundaries of the leasing area;

(D) provide for cancellation of a natural gas lease, with payment of the fair value of the lease rights canceled, if the Secretary determines that hydrocarbons other than natural gas and natural gas liquids will be the predominant production from the lease; and

(E) provide that, at the request and with the consent of the Governor of the State adjacent to the lease area, and with the consent of the lessee, an existing natural gas lease may be converted, without an increase in the rental royalty rate and without further payment in the nature of a lease bonus, to a lease under section 8(b) of the Outer Continental Shelf Lands Act (43 U.S.C. 1337(b)), in accordance with a process, to be established by the Secretary, that requires—

(i) consultation by the Secretary with the Governor of the State and the lessee with respect to the operating conditions of the lease, taking into consideration environmental resource conservation and recovery, economic factors, and other factors, as the Secretary determines to be relevant; and

(ii) compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.).

(3) EFFECT OF OTHER LAWS.—Any Federal law (including regulations) that applies to an oil and gas lease on the outer Continental Shelf shall apply to a natural gas lease issued under this subsection.

(h) EXCHANGE OF LEASES FOR AREAS LOCATED WITHIN 100 MILES OF STATES IMPOSING A MORATORIUM.—

(1) IN GENERAL.—Effective beginning on the date that is 180 days after the date of enactment of this Act, the lessee of an oil and gas lease in existence on the date of enactment of this Act for an area located completely within 100 miles of the coastline and within the Adjacent Zones of States that have extended a moratorium under subsection (c) shall have the option, without compensation, of exchanging the lease for a new oil and gas lease having a primary term of 5 years.

(2) TRACTS.—For the area subject to the new lease, the lessee may select any unleased tract—

(A) at least part of which is located within the area between 100 and 125 miles from the coastline; and

(B) that is located—

(i) completely beyond 125 miles from the coastline; and

(ii) within the same Adjacent Zone of the adjacent State as the lease being exchanged.

(3) ADMINISTRATIVE PROCESS.—

(A) IN GENERAL.—The Secretary shall establish a reasonable administrative process through which a lessee may exercise the option of the lessee to exchange an oil and gas lease for a new oil and gas lease in accordance with this subsection.

(B) RELATIONSHIP TO OTHER LAWS.—An exchange of leases conducted in accordance with this subsection (including the issuance of a new lease)—

(i) shall not be considered to be a major Federal action for purposes of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.); and

(ii) shall be considered in compliance with the Outer Continental Shelf Lands Act (43 U.S.C. 1331 et seq.).

(C) WITHDRAWAL.—The Secretary shall issue a new lease in exchange for the lease being exchanged notwithstanding that the area that will be subject to the lease may be withdrawn from leasing under the Outer Continental Shelf Lands Act (43 U.S.C. 1331 et seq.) or otherwise unavailable for leasing under any other law.

(4) PRIORITY.—

(A) BONUS BID.—The Secretary shall give priority in the lease exchange process under this subsection based on the amount of the original bonus bid paid for the issuance of each lease to be exchanged.

(B) EXCHANGE OF PARTIAL TRACTS FOR FULL TRACTS.—The Secretary shall allow leases covering partial tracts to be exchanged for leases covering full tracts under this subsection conditioned on payment of additional bonus bids on a per-acre basis, as determined based on the average per acre of the original bonus bid per acre for the partial tract being exchanged.

(5) CANCELLATION OF LEASE.—As part of the lease exchange process under this subsection, the Secretary shall cancel a lease that is exchanged under this subsection.

(6) CONDITIONS FOR LEASE EXCHANGE.—For a lease to be cancelled and exchanged under this subsection—

(A) each lessee holding an interest in the lease must consent to cancellation of the leasehold interest of the lessee;

(B) each lessee must waive any rights to bring any litigation against the United States related to the transaction; and

(C) the plugging and abandonment requirements for any well located on any lease to be cancelled and exchanged under this subsection must be complied with by the lessees prior to the cancellation and exchange.

(i) OPERATING RESTRICTIONS.—A new lease issued under this section shall be subject to such national defense operating restrictions on the outer Continental Shelf tract covered by the new lease as apply on the date of issuance of the new lease.

(j) DISPOSITION OF COVERED REVENUES FROM MORATORIUM AREAS.—

(1) IN GENERAL.—Notwithstanding section 9 of the Outer Continental Shelf Lands Act (43 U.S.C. 1338) and subject to the other provisions of this subsection, for each applicable fiscal year, the Secretary of the Treasury shall deposit—

(A) 50 percent of covered revenues in the general fund of the Treasury; and

(B) 50 percent of covered revenues in a special account in the Treasury from which the Secretary shall disburse—

(i) 75 percent to covered States in accordance with paragraph (2); and

(ii) 25 percent to provide financial assistance to States in accordance with section 6 of the Land and Water Conservation Fund Act of 1965 (16 U.S.C. 460*l*-8), which shall be considered income to the Land and Water

Conservation Fund for purposes of section 2 of that Act (16 U.S.C. 460*l*-5).

(2) ALLOCATION AMONG COVERED STATES AND COASTAL POLITICAL SUBDIVISIONS.—

(A) ALLOCATION AMONG COVERED STATES FOR FISCAL YEAR 2007 AND THEREAFTER.—

(i) IN GENERAL.—Subject to clause (ii), effective for fiscal year 2007 and each fiscal year thereafter, the amount made available under paragraph (1)(B)(i) shall be allocated to each covered State in amounts (based on a formula established by the Secretary by regulation) that are inversely proportional to the respective distances between the point on the coastline of each covered State that is closest to the geographic center of the applicable leased tract and the geographic center of the leased tract.

(ii) MINIMUM ALLOCATION.—The amount allocated to a covered State each fiscal year under clause (i) shall be at least 10 percent of the amounts available under paragraph (1)(B)(i).

(B) PAYMENTS TO COASTAL POLITICAL SUBDIVISIONS.—

(i) IN GENERAL.—The Secretary shall pay 20 percent of the allocable share of each covered State, as determined under subparagraph (A), to the coastal political subdivisions of the covered State.

(ii) ALLOCATION.—The amount paid by the Secretary to coastal political subdivisions shall be allocated to each coastal political subdivision in accordance with subparagraphs (B), (C), (D), and (E) of section 31(b)(4) of the Outer Continental Shelf Lands Act (43 U.S.C. 1356a(b)(4)).

(3) TIMING.—The amounts required to be deposited under paragraph (1)(B) for the applicable fiscal year shall be made available in accordance with that paragraph during the fiscal year immediately following the applicable fiscal year.

(4) AUTHORIZED USES.—

(A) IN GENERAL.—Subject to subparagraph (B), each covered State and coastal political subdivision shall use all amounts received under paragraph (2) in accordance with all applicable Federal and State laws, only for 1 or more of the following purposes:

(i) Projects and activities for the purposes of coastal protection, including conservation, coastal restoration, hurricane protection, and infrastructure directly affected by coastal wetland losses.

(ii) Mitigation of damage to fish, wildlife, or natural resources.

(iii) Implementation of a federally-approved marine, coastal, or comprehensive conservation management plan.

(iv) Mitigation of the impact of outer Continental Shelf activities through the funding of onshore infrastructure projects.

(v) Planning assistance and the administrative costs of complying with this section.

(B) LIMITATION.—Not more than 3 percent of amounts received by a covered State or coastal political subdivision under paragraph (1)(B) may be used for the purposes described in subparagraph (A)(v).

(5) ADMINISTRATION.—Amounts made available under paragraph (1)(B) shall—

(A) be made available, without further appropriation, in accordance with this subsection;

(B) remain available until expended; and

(C) be in addition to any amounts appropriated under—

(i) the Outer Continental Shelf Lands Act (43 U.S.C. 1331 et seq.);

(ii) the Land and Water Conservation Fund Act of 1965 (16 U.S.C. 4601–4 et seq.); or

(iii) any other provision of law.

(k) REPEAL OF REQUIREMENT TO CONDUCT COMPREHENSIVE INVENTORY OF OCS OIL AND NATURAL GAS RESOURCES.—Section 357 of the Energy Policy Act of 2005 (42 U.S.C. 15912) is repealed.

SA 4748. Mr. ALLEN submitted an amendment intended to be proposed to amendment SA 4713 proposed by Mr. FRIST to the bill S. 3711, to enhance the energy independence and security of the United States by providing for exploration, development, and production activities for mineral resources in the Gulf of Mexico, and for other purposes; which was ordered to lie on the table; as follows:

At the end of the amendment, add the following:

SEC. 6. OFFSHORE OIL AND GAS LEASING IN AREAS OFF THE STATE OF VIRGINIA.

(a) DEFINITIONS.—In this section:

(1) ADJACENT ZONE.—The term ''Adjacent Zone'' means the Adjacent Zone of the State, as defined by the lines extending seaward and defining the adjacent Zone of the State indicated on the map entitled ''Atlantic OCS Region State Adjacent Zones and OCS Planning Areas'', dated September 2005 and on file in the Office of the Director of the Minerals Management Service.

(2) COASTLINE.—The term ''coastline'' has the meaning given the term ''coast line'' in section 2 of the Submerged Lands Act (43 U.S.C. 1301).

(3) COVERED REVENUES.—

(A) IN GENERAL.—The term ''covered revenues'' means all rentals, royalties, bonus bids, and other sums due and payable to the United States from leases entered into on or after the date of enactment of this Act in the Adjacent Zone.

(B) EXCLUSIONS.—The term ''covered revenues'' does not include revenues—

(i) from the forfeiture of a bond or other surety securing obligations other than royalties, civil penalties, or royalties taken by the Secretary in-kind and not sold; or

(ii) generated from leases subject to section 8(g) of the Outer Continental Shelf Lands Act (43 U.S.C. 1337(g)).

(4) NEIGHBORING STATE.—The term ''Neighboring State'' means any State that has a common boundary at the coastline with the State.

(5) STATE.—The term ''State'' means the Commonwealth of Virginia.

(b) PROHIBITION AGAINST LEASING.—

(1) UNAVAILABLE FOR LEASING WITHOUT STATE REQUEST.—Except as otherwise provided in this section, the Secretary shall not offer for leasing for oil and gas, or natural gas, any area in the Adjacent Zone that is within 50 miles of the coastline of the State and that was withdrawn from disposition by leasing in the Atlantic OCS Region under the ''Memorandum on Withdrawal of Certain Areas of the United States Outer Continental Shelf from Leasing Disposition'', from 34 Weekly Comp. Pres. Doc. 1111, dated June 12, 1998.

(2) AREAS BETWEEN 50 AND 100 MILES FROM THE COASTLINE.—Unless the State petitions under subsection (c) by the date that is 1 year after the date of enactment of this Act for natural gas leasing or by June 30, 2009, for oil and gas leasing, the Secretary shall offer for leasing any area in the Adjacent Zone that is more than 50 miles, but less than 100 miles, from the coastline of the State that was withdrawn from disposition by leasing in the Atlantic OCS Region under the ''Memorandum on Withdrawal of Certain Areas of the United States Outer Continental Shelf from Leasing Disposition'', from 34 Weekly Comp. Pres. Doc. 1111, dated June 12, 1998.

(c) PETITION FOR LEASING.—

(1) IN GENERAL.—The Governor of the State, on the concurrence of the legislature of the State, may submit to the Secretary a petition requesting that the Secretary make available any area that is—

(A) within the Adjacent Zone, as described in subsection (b); and

(B) is greater than—

(i) 25 miles from any point on the coastline of a Neighboring State for the conduct of offshore leasing, pre-leasing, and related activities with respect to natural gas leasing; or

(ii) 50 miles from any point on the coastline of a Neighboring State for the conduct of offshore leasing, pre-leasing, and related activities with respect to oil and gas leasing.

(2) PETITION BY STATE.—

(A) IN GENERAL.—The State may petition for leasing any other area within the Adjacent Zone if—

(i) leasing is allowed in the similar area of the Adjacent Zone; or

(ii) if not allowed, the State, acting through the Governor of the State, expresses the concurrence of the State with the petition.

(B) FINDING.—The Secretary shall only consider a petition under subparagraph (A) on—

(i) making a finding that leasing is allowed in a similar area of the Adjacent Zone; or

(ii) receipt of the concurrence of the State.

(C) DATE OF RECEIPT.—The date of receipt by the Secretary of the concurrence by the State shall constitute the date of receipt of the petition for the area for which the concurrence applies.

(D) LIMITATIONS ON LEASING.—If, as of the date of petition by the State, the Adjacent Zone contains leased tracts, the State, in the petition of the State, may condition new leasing for oil and gas, or natural gas, for tracts within 25 miles of the coastline of the State, by—

(i) requiring a net reduction in the number of production platforms;

(ii) requiring a net increase in the average distance of production platforms from the coastline;

(iii) limiting permanent surface occupancy on new leases to areas that are more than 10 miles from the coastline;

(iv) limiting some tracts to being produced from shore or from platforms located on other tracts; or

(v) including other conditions that the State considers to be appropriate as long as the Secretary does not determine that production is made economically or technically impracticable or otherwise impracticable.

(3) ACTION BY SECRETARY.—

(A) IN GENERAL.—Not later than 90 days after the date of receipt of a petition under paragraph (1), the Secretary shall approve the petition, unless the Secretary determines that leasing the area would be likely to cause serious harm or damage to the marine resources of the Adjacent Zone.

(B) ENVIRONMENTAL ASSESSMENT.—Before approving the petition, the Secretary shall complete an environmental assessment that documents the anticipated environmental effects of leasing in the area covered by the petition.

(4) FAILURE TO ACT.—If the Secretary fails to approve or deny a petition in accordance with paragraph (3), the petition shall be considered to be approved as of the date that is 90 days after the date of receipt of the petition.

(d) OPTION TO EXTEND WITHDRAWAL FROM LEASING WITHIN CERTAIN AREAS OF THE OUTER CONTINENTAL SHELF.—

(1) IN GENERAL.—The State, through the Governor of the State and on the concurrence of the legislature of the State, may extend, for a period of time of up to 5 years for each extension, the withdrawal from leasing of all or part of any area within the Adjacent Zone located more than 50 miles, but less than 100 miles, from the coastline of the State that is subject to subsection (b)(2).

(2) MULTIPLE EXTENSIONS.—The State may extend a withdrawal described in paragraph (1) for any particular area—

(A) multiple times; but

(B) not more than once per calendar year.

(3) SEPARATE EXTENSIONS.—The State shall prepare separate extensions, with separate votes by the legislature of the State, for the withdrawal of areas for oil and gas leasing and for natural gas leasing.

(4) AREAS.—An extension by the State may affect some areas to be withdrawn from all leasing and some areas to be withdrawn only from 1 type of leasing.

(e) EFFECT OF OTHER LAWS.—

(1) IN GENERAL.—Adoption by the State of any constitutional provision, or enactment of any State law, that has the effect, as determined by the Secretary, of restricting the Governor or Legislature from exercising full discretion relating to subsection (g) or (h) shall, for the duration of the restriction, prohibit—

(A) any sharing of qualified outer Continental Shelf revenues or covered revenues under this Act with the State and the coastal political subdivisions of the State; and

(B) the State from exercising any authority under subsection (d).

(2) DEADLINE.—The Secretary shall make the determination of the existence of a restrictive constitutional provision or State law under paragraph (1) not later than 30 days after the date of receipt of a petition by any outer Continental Shelf lessee or coastal State.

(f) DISPOSITION OF COVERED REVENUES FROM STATE.—

(1) IN GENERAL.—Notwithstanding section 9 of the Outer Continental Shelf Lands Act (43 U.S.C. 1338) and subject to the other provisions of this subsection, for each applicable fiscal year, the Secretary of the Treasury shall deposit—

(A) 50 percent of covered revenues in the general fund of the Treasury; and

(B) 50 percent of covered revenues in a special account in the Treasury from which the Secretary shall disburse—

(i) 75 percent to the State in accordance with paragraph (2); and

(ii) 25 percent to provide financial assistance to States in accordance with section 6 of the Land and Water Conservation Fund Act of 1965 (16 U.S.C. 460*l*-8), which shall be considered income to the Land and Water Conservation Fund for purposes of section 2 of that Act (16 U.S.C. 460*l*-5).

(2) ALLOCATION AMONG STATE AND COASTAL POLITICAL SUBDIVISIONS.—

(A) ALLOCATION TO STATE FOR FISCAL YEAR 2007 AND THEREAFTER.—Effective for fiscal year 2007 and each fiscal year thereafter, the amount made available under paragraph (1)(B)(i) shall be allocated to the State.

(B) PAYMENTS TO COASTAL POLITICAL SUBDIVISIONS.—

(i) IN GENERAL.—The Secretary shall pay 20 percent of the allocable share of the State, as determined under subparagraph (A), to the coastal political subdivisions of the State.

(ii) ALLOCATION.—The amount paid by the Secretary to coastal political subdivisions shall be allocated to each coastal political subdivision in accordance with subparagraphs (B) and (E) of section 31(b)(4) of the Outer Continental Shelf Lands Act (43 U.S.C. 1356a(b)(4)).

(3) TIMING.—The amounts required to be deposited under paragraph (1)(B) for the applicable fiscal year shall be made available in accordance with that paragraph during the fiscal year immediately following the applicable fiscal year.

(4) AUTHORIZED USES.—

(A) IN GENERAL.—Subject to subparagraph (B), the State and each coastal political subdivision shall use all amounts received under paragraph (2) in accordance with all applicable Federal and State laws, only for 1 or more of the following purposes:

(i) Projects and activities for the purposes of coastal protection, including conservation, coastal restoration, sand or beach replenishment, or hurricane protection.

NOTICE OF MEETING

COMMITTEE ON INDIAN AFFAIRS

Mr. MCCAIN. Mr. President, I would like to announce that the Committee on Indian Affairs will meet on Wednesday, August 2, 2006, at 9:30 a.m. in Room 485 of the Russell Senate Office Building to conduct a business meeting on S. 374, the Tribal Parity Act; S. 480, the Thomasina E. Jordan Indian Tribes of Virginia Federal Recognition Act of 2005; S. 660, the Lumbee Recognition Act; S. 1439, the Indian Trust Reform Act of 2005; and S. 1535, the Cheyenne River Sioux Tribe Equitable Compensation Amendments Act of 2005.

Those wishing additional information may contact the Indian Affairs Committee at 202–224–2251.

The PRESIDING OFFICER. Without objection, it is so ordered.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON FINANCE

Mr. ALLEN. Mr. President, I ask unanimous consent that the Committee on Finance be authorized to meet during the session on Monday, July 31, 2006, immediately following the next vote on the Senate Floor (tentatively scheduled to occur at 5:30 p.m.), in the President's Room, S–216 of the Capitol, to consider approving recommendations on proposed legislation implementing the U.S.-Peru Trade Promotion Agreement, and to consider favorably reporting S. 3495, to authorize the extension of nondiscriminatory treatment (normal trade relations treatment) to the products of Vietnam.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON FOREIGN RELATIONS

Mr. ALLEN. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on Monday, July 31, 2006, at 3 p.m. to hold a hearing on nominations.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON VETERANS' AFFAIRS

Mr. ALLEN. Mr. President, I ask unanimous consent that the Committee on Veterans' Affairs be authorized to meet during the session of the Senate on Monday, July 31, 2006, to hold a markup to consider the nominations of Patrick W. Dunne to be Assistant Secretary for Policy & Planning and Thomas E. Harvey to be Assistant Secretary for Congressional Affairs, Department of Veterans' Affairs.

The meeting will take place in the Reception Room off the Senate floor in the Capitol following the first rollcall vote of the day for the Senate currently scheduled for 5:30 p.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

AMENDING THE IRAN AND LIBYA SANCTIONS ACT OF 1996

Mr. SPECTER. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of H.R. 5877, which was received from the House.

The PRESIDING OFFICER. The clerk will report the bill by title.

The bill clerk read as follows:

A bill (H.R. 5877) to amend the Iran and Libya Sanctions Act of 1996 to extend the authorities provided in such Act until September 29, 2006.

There being no objection, the Senate proceeded to consider the bill.

Mr. SPECTER. Mr. President, I ask unanimous consent that the bill be read a third time and passed, the motion to reconsider be laid upon the table, and that any statements relating to the bill be printed in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The bill (H.R. 5877) was ordered to a third reading, was read the third time, and passed.

EXPRESSING SENSE OF THE SENATE REGARDING EFFECTIVE TREATMENT AND ACCESS TO CARE

Mr. SPECTER. Mr. President, on behalf of the leader, I ask unanimous consent that the HELP Committee be discharged from further consideration and the Senate proceed to S. Res. 420.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report the resolution by title.

The bill clerk read as follows:

A resolution (S. Res. 420) expressing the sense of the Senate that effective treatment and access to care for individuals with psoriasis and psoriatic arthritis should be improved.

There being no objection, the Senate proceeded to consider the resolution.

Mr. SPECTER. Mr. President, I ask unanimous consent that the resolution be agreed to, the preamble be agreed to, and the motion to reconsider be laid upon the table.

The PRESIDING OFFICER. Without objection, it is so ordered.

The resolution (S. Res. 420) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

S. RES. 420

Whereas psoriasis and psoriatic arthritis are serious, chronic, inflammatory, disfiguring, and life-altering diseases that require sophisticated medical intervention and care;

Whereas, according to the National Institutes of Health, between 5,800,000 citizens and 7,500,000 citizens of the United States are affected by psoriasis;

Whereas psoriasis and psoriatic arthritis are—

(1) painful and disabling diseases with no cure; and